

Regulatory Statutes concerning the White Paper on the Medical Care of the Severely Injured

Contents

1. Preamble.....	2
2. TraumaNetwork (Re-)Certification	3
3. Certification of Local TraumaCentres	5
4. Certification of Regional TraumaCentres	10
5. Certification of Supraregional TraumaCentres	16

1. Preamble

The regulatory statutes concerning the procedure of the TraumaNetzwerk DGU® (TraumaNetwork project operated by the German Trauma Society) have been compiled on the basis of the currently valid White Paper on the Medical Care of the Severely Injured 3.0 (Weißbuch Schwerverletztenversorgung 3.0).

Their purpose is to facilitate the preparation and review of (re-)certification and (re-)auditing processes.

They were compiled by the TraumaNetzwerk DGU committee, with the assistance of experts from the professional association and, alongside the White Paper on the Medical Care of the Severely Injured, serve as the basis for the auditing of TraumaCentres and the certification of TraumaNetworks. Unless otherwise stated in these regulatory statutes, the requirements formulated in the White Paper on the Medical Care of the Severely Injured 3.0 apply.

The objective of the application of the white paper and its regulatory statutes is to ensure the same rate of survival and the best possible quality of life for all severely injured patients, at every centre and at all times.

Version 1.0 of the regulatory statutes stipulated here are valid for all audits and certifications in Belgium performed from 01/10/2025 onwards.

2. TraumaNetwork (Re-)Certification

Stipulation in the White Paper	Test criterion
Number of centres within the TraumaNetwork Recommended requirement: 5 TraumaCenters in total: <ul style="list-style-type: none"> • minimum 1 x ÜTZ • minimum 1 x RTZ • minimum 1 x LTZ 	In case there is no ÜTZ in the TNW, a cooperation agreement must be concluded with an ÜTZ from a neighboring TNW
Agreement, incl. annexes	The documents made available to download in the Trauma Portal <ul style="list-style-type: none"> • “Agreement” PDF template and • “Annexes to the agreement” Word templates must be used.
Quality Circle (QC) meeting within the TraumaNetwork <ul style="list-style-type: none"> • Minimum requirement: 1 meeting per year • The invitation should be issued at least 4 weeks prior to the date of the meeting • The TraumaNetwork annual report must be discussed at least once a year • The Quality Circle meeting can take place in conjunction with network meetings (see below) 	<ul style="list-style-type: none"> • The invitation to the meeting must be submitted with the documents for (re-)certification • This will be evidenced in the minutes of the meeting • The following persons must be invited: <ul style="list-style-type: none"> ○ Heads of the individual TraumaCentres or their representatives ○ Prehospital care physicians (EMS medical directors, chief emergency physicians, etc.) ○ Heads of rescue coordination centres ○ Representatives of physicians, surgeons and other staff involved in the care of severely injured patients in hospitals of the TraumaNetwork

<p>TraumaNetwork meetings</p> <ul style="list-style-type: none"> • Minimum requirement: 1 meeting per year • The invitation should be issued at least 4 weeks prior to the date of the meeting • The TraumaNetwork meetings can take place in conjunction with the Quality Circle (see above) 	<ul style="list-style-type: none"> • The invitation to the meeting must be submitted with the documents for (re-)certification • The following persons must be invited: <ul style="list-style-type: none"> ○ Director of the individual TraumaCentres or their representatives ○ Prehospital care physicians (EMS medical directors, chief emergency physicians, etc.) ○ Heads of rescue coordination centres ○ Representatives of physicians, surgeons and other staff involved in the care of severely injured patients in hospitals of the trauma network • This must be evidenced in the minutes of the meeting
<p>Advanced Training Events</p> <ul style="list-style-type: none"> • Minimum requirement: 1 event per year • Interdisciplinary/inter-professional advanced training event, involving hospital personnel, emergency physicians, rescue service personnel, and personnel from rehabilitation institutions 	<ul style="list-style-type: none"> • This must be evidenced in the schedule/agenda and must be submitted with the documents for (re-)certification. • A mass-casualty incident/mass-casualty terrorist incident exercise can be considered as an advanced training course
<p>Mass-casualty incident/mass-casualty terrorist incident exercise</p> <p>One mass-casualty incident/mass-casualty terrorist incident exercise should take place within all centres of the TraumaNetwork per certification cycle. Alternatively, an advanced training course on the topic can be held, lasting at least 90 minutes.</p>	<ul style="list-style-type: none"> • This must be evidenced in the schedule/agenda and must be submitted with the documents for (re-)certification.

3. Certification of Local TraumaCentres

Stipulation in the White Paper	Test criterion
Responsible trauma surgery unit (trauma unit)	<ul style="list-style-type: none"> Department of Orthopaedics/Trauma Surgery → Task: inpatient care for trauma patients Operational unit with its own (designated) beds Interdisciplinary ward rounds/meetings on all trauma patients (once a week) → not mandatory ward rounds Staff composition: <ul style="list-style-type: none"> Medical management: Orthopaedic Trauma Surgeon/Trauma Surgeon → Mainly responsible for trauma patients from the resuscitation room/operation to discharge, including rehabilitation planning (if necessary) Deputy management Other employees (medical staff, nursing staff, etc.)
Organizational chart for the care of severely injured patients	<ul style="list-style-type: none"> Definition of Trauma Team → Task: Care of the patient in the resuscitation room Content: <ul style="list-style-type: none"> Presentation of the involved specialties, including attendance and task definitions Regulation of which discipline manages which injuries At least one surgeon in the leadership team with assigned appropriate responsibilities Definition of Trauma Leader (preferably a surgeon) with independence in emergency care and ongoing treatment, own personnel resources, own access to operating room capacity, and possibly authority to issue instructions Clear depiction of the decision-making chain
Basic interdisciplinary team in the resuscitation room (24/7 presence in the hospital)	<ul style="list-style-type: none"> 1 specialist (or surgeon who provides a standard of care commensurate with the level of a specialist) in orthopaedics/ trauma surgery <i>Or</i> 1 specialist (or surgeon who provides a standard of care commensurate with the level of a specialist) in for emergency medicine (Emergency Physician) <i>or</i> 1 specialist (or surgeon who provides a standard of care commensurate with the level of a specialist) in visceral surgery <i>or</i> 1 specialist (or surgeon who provides a standard of care commensurate with the level of a specialist) in general surgery

	<p>→ The partner/ consultant (designated in the service plan) decides on the standard of care commensurate with the level of a specialist</p> <ul style="list-style-type: none"> 1 specialist (or physician who provides a standard of care commensurate with the level of a specialist) in anaesthesiology → Specialist must be present with patients in the resuscitation room (written rule must be in place), 24/7 presence in the hospital not compulsory 1 emergency department nurse → registered, alternatively registered paramedic 1 anaesthetic nurse 1 medical radiology technician
<p>Extended resuscitation room team (Presence within 30 minutes)</p> <p>All disciplines must be available for every resuscitation room emergency alert</p>	<ul style="list-style-type: none"> 1 specialist in orthopaedics/ trauma surgery (partner/Consultant) 1 specialist Emergency Physician (Partner/Consultant) 1 specialist in visceral or general surgery (Partner/Consultant) 1 specialist in anaesthesiology (Partner/Consultant) 1 specialist in radiology → can be covered by means of 24-hour teleradiology availability in accordance with the Radiation Protection Act
<p>Training in the medical care of the severely injured</p>	<ul style="list-style-type: none"> Valid ATLS certificates must be verified for all trauma specialists and emergency physicians deployed in the resuscitation room → In addition, for all other doctors deployed in the resuscitation room (First Service and Partner/Consultant), an ATLS certificate is recommended Equivalent: ETC certificate (valid for 5 years)
<p>Emergency department trauma unit</p>	<ul style="list-style-type: none"> Resuscitation room size at least 25 m² X-ray equipment must be available in the resuscitation room CT in the trauma room or an adjacent room → maximum distance of 50 m The resuscitation room does not have to have an operating theatre
<p>Equipment for the treatment of the severely injured - Emergency department</p>	<ul style="list-style-type: none"> Blood depot → 24/7 availability → Requirements for an external depot: The following must be in place within 60-90 minutes: <ol style="list-style-type: none"> Required reserves Cross-matched ECs Laboratory → Results must be available 24/7 → Requirements for an external laboratory: The following must be determined within 60 minutes: <ol style="list-style-type: none"> Blood count

	<ol style="list-style-type: none"> 2. Simple coagulation diagnostics (primary haemostasis, secondary haemostasis and heparin activity monitoring) 3. Clinical/chemical parameters (electrolytes, BGA, creatinine) <ul style="list-style-type: none"> • Ventilator • Pulse oximetry system • Extraction system • Capnography system • Video laryngoscope • Bronchoscopy • Pleural drainage • Blood gas analyser (BGA unit) → Located in the emergency department! • Fast infusion system • ECG monitor • Defibrillator • Invasive blood pressure measurement • Ext. pelvic stabilisation (belt) • Suprapubic urine drainage system • Emergency medicines • Diagnostic imaging: <ul style="list-style-type: none"> ○ Ultrasound unit, vascular doppler ○ Conventional X-ray diagnostics Alternatively: Mobile X-ray unit ○ CT • Rail and extension systems • Tempering systems <ul style="list-style-type: none"> ○ For patients ○ For infusion and blood • Cell-Saver • Resuscitation room clock • Intraosseous infusion <p>Desirable:</p> <ul style="list-style-type: none"> • Microbiology • Helipad (24/7 operation) • Diagnostic imaging: <ul style="list-style-type: none"> ○ Angiography workstation with intervention ○ MRI
Equipment for the provision of medical care to the severely injured - operating room	<ul style="list-style-type: none"> • Laparotomy set • Thoracotomy set • Mechanical pelvic stabilisation • Pericardial puncture kit • External fixator – 2 sets • Intramedullary system • Plate system
Intensive care unit	The ability to provide intensive care treatment to a severely injured patient must be maintained (24/7).

Case numbers	<p>Documentation of at least 5 patients who are included in the basic group of patients of the DGU TraumaRegister (M-AIS 3+ / M-AIS 2 patients who died or were treated on the intensive care unit) each year → At re-audit, patient numbers are averaged across the three-year certification interval → If the case numbers are not achieved on account of a lack of declaration of consent, the following is required:</p> <ul style="list-style-type: none"> ○ Explanation of the method used to collect the declaration of consent ○ Alternative proof of the treated cases
Quality assurance	<ul style="list-style-type: none"> • Protocol for organ donation • “Resuscitation room emergency alert/central group call” SOP • Medical Care of the Severely Injured SOP taking the S3 guidelines into account • Risk management evidence • reporting of the electronic hospital information system • “Screening upon admission and further procedure in case of infections (multi-resistant germs)” SOP • “Avoiding near misses” SOP
Events	<ol style="list-style-type: none"> 1. Participation in network meetings and TraumaNetwork Quality Circle meetings → At least 1x per year → Evidenced by means of certificates of participation 2. Informing all participating doctors and professional groups regarding the results of the DGU TraumaRegister → At least 1x per year 3. Internal Clinic Quality Circle → At least 2x per year → Evidenced by means of minutes 4. Trauma Surgery or Interdisciplinary Morbidity & Mortality Conference → Evidenced by means of minutes
Training, advanced training, and further training of employees	<p>Desirable:</p> <ul style="list-style-type: none"> • Courses on technical competencies: e.g. AO courses, DSTC, Lifelike Fracture Simulation • Courses on procedural competencies: e.g. ATLS, ETC, TDSC • Courses on interpersonal competencies: e.g. Human Factors Training

Mass-casualty incident/mass-casualty terrorist incident exercise	<ul style="list-style-type: none"> • 2 certificates (TDSC/ MRMI or similar) are recommended • Hospital emergency response plan tailored to mass-casualty incidents/mass-casualty terrorist incidents (within the past 3 years) <p>Contents:</p> <ul style="list-style-type: none"> ○ HR concept: Definition of responsible persons - red/yellow/green (decision-makers, persons responsible for triage, etc.) ○ Triage concept (incl. room concept and route concept) ○ Emergency alert concept ○ Admission concept (cf. "Admission capacity" tables further below) ○ Security concept (incl. staff access regulations) ○ Equipment concept (incl. emergency surgical instrument sets) <ul style="list-style-type: none"> → Evidence of: Pelvic C-clamps, non-invasive pelvic stabilisation equipment, tourniquets, haemostyptics, antiseptic solutions ○ Room concept (identification of treatment areas - red/yellow/green) <ul style="list-style-type: none"> → Hospital emergency response plan must be in place • Information/training of employees regarding hospital emergency response plan <ul style="list-style-type: none"> → 1x per 3 years → Proof of invitation/agenda • Exercises and emergency simulations <ul style="list-style-type: none"> → 1x per 3 years
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Admission capacities within the first hour for each triage category (TI-TIII):

Service level	TI (red)	TII (yellow)	TIII (green)
Local TC	0	2	8

Admission capacities after start of emergency plan:

Service level	TI (red)	TII (yellow)	TIII (green)
Local TC	0	4	16

4. Certification of Regional TraumaCentres

White Paper Stipulation	Test criterion
Responsible trauma surgery unit (trauma unit)	<ul style="list-style-type: none"> • Department of Orthopaedics/Trauma Surgery → Task: inpatient care for trauma patients • Operational unit with its own (designated) beds • Interdisciplinary ward rounds/meetings on all trauma patients (once a week) → not mandatory ward rounds • Staff composition: <ul style="list-style-type: none"> ▪ Medical management: Orthopaedic Trauma Surgeon/Trauma Surgeon → Mainly responsible for trauma patients from the resuscitation room/operation to discharge, including rehabilitation planning (if necessary) ▪ Deputy management ▪ Other employees (medical staff, nursing staff, etc.)
Organizational chart for the care of severely injured patients	<ul style="list-style-type: none"> • Definition of Trauma Team → Task: Care of the patient in the resuscitation room • Content: <ul style="list-style-type: none"> ○ Presentation of the involved specialties, including attendance and task definitions ○ Regulation of which discipline manages which injuries • At least one surgeon in the leadership team with assigned appropriate responsibilities • Definition of Trauma Leader (preferably a surgeon) with independence in emergency care and ongoing treatment, own personnel resources, own access to operating room capacity, and possibly authority to issue instructions • Clear depiction of the decision-making chain

<p>Basic interdisciplinary team in the resuscitation room (24/7 presence in the hospital)</p>	<ul style="list-style-type: none"> • 1 specialist (or surgeon who provides a standard of care commensurate with the level of a specialist) in orthopaedics/ trauma surgery → The senior consultant (designated in the service plan) decides on the standard of care commensurate with the level of a specialist <i>and</i> • 1 specialist (or surgeon who provides a standard of care commensurate with the level of a specialist) in Emergency medicine (Emergency Physician) • 1 resident in orthopaedics/ trauma surgery <i>or</i> • 1 resident in Emergency medicine (Emergency Physician) <i>or</i> • 1 resident in visceral and/or general surgery • 1 specialist (or physician who provides a standard of care commensurate with the level of a specialist) in anaesthesiology → Specialist must be present with patients in the resuscitation room (written rule must be in place), 24/7 presence in the hospital not essential • 2 emergency department nurses → registered, alternatively registered paramedic • 1 anaesthetic nurse • 1 medical radiology technician
<p>Extended resuscitation room team (Presence within 30 minutes)</p> <p>All disciplines must be available for every resuscitation room emergency alert</p>	<ul style="list-style-type: none"> • 1 specialist in orthopaedics/ trauma surgery with an additional qualification in special trauma surgery (partner/ consultant) <i>and</i> • 1 specialist in Emergency medicine (Emergency Physician) (partner/ consultant) • 1 specialist in visceral or general surgery (partner/ consultant) • 1 specialist in anaesthesiology (partner/ consultant) • 1 specialist in radiology → can be covered by means of 24-hour teleradiology availability in accordance with the local legislation • 1 specialist in neurosurgery* • 1 specialist in vascular surgery* • 2 operating room nurses <p>→ Disciplines as main specialist departments on site</p> <p>* In exceptional cases, proof of cooperation agreement possible (cf. "Main department & cooperations" section)</p>

Main department & cooperations	<ul style="list-style-type: none"> • Definition of main department: at least 3 specialists in full-time positions • Cooperation possible for <ul style="list-style-type: none"> ◦ neurosurgery ◦ vascular surgery → If no main department in the hospital • Cooperation with another TraumaCenter (preferably RTZ or ÜTZ) → The collaborating hospital must also be recognized as a TraumaCenter and should be certified at least at the same level. • The following content must be regulated: <ul style="list-style-type: none"> ◦ Stipulation of the contractual parties ◦ Underlying guideline (White Paper in its currently valid edition) ◦ Reason for cooperation (identification of the relative specialist department) ◦ Definition of the scope of service/contractual object: <u>Transfer contract:</u> <ul style="list-style-type: none"> ▪ Further treatment in another hospital ▪ Necessary structural resources for surgical treatment and intensive medical care must be present within the transfer clinic/hospital ▪ Guarantee of the prompt transfer of the patient, 24/7 (if necessary, a regulation regarding communication if the agreed service cannot be provided in acute cases) ▪ Patient transport time of no more than 30 minutes (form of transport) ▪ Tele-medical cooperation ◦ Signatures of the managing directors and, if applicable, the clinic/hospital directors ◦ In addition, regulations on the following are also worthwhile: <ul style="list-style-type: none"> ▪ Remuneration and accounting ▪ Termination periods • Furthermore, statutory regulations remain unaffected.
Training in trauma patient care	<ul style="list-style-type: none"> • Valid ATLS certificates must be verified for all trauma specialists and emergency physicians deployed in the resuscitation room → In addition, for all other doctors deployed in the resuscitation room (First Service and Partner/Consultant), an ATLS certificate is recommended • Equivalent: ETC certificate (valid for 5 years)

A&E trauma unit	<ul style="list-style-type: none"> • Resuscitation room at least 25 m² • X-ray equipment must be available in the resuscitation room • CT in the resuscitation room or an adjacent room → maximum distance of 50 m • In case of new construction/renovation planning: CT in the resuscitation room or adjoining room • An operating theatre is not required in the resuscitation room
Equipment for the treatment of the severely injured - Emergency department	<ul style="list-style-type: none"> • Blood depot • Laboratory → Results must be available 24/7 • Microbiology • Ventilator • Pulse oximetry system • Extraction system • Capnography system • Video laryngoscope • Bronchoscopy • Pleural drainage • Blood gas analyser (BGA unit) → Location in emergency department! • Fast infusion system • ECG monitor • Defibrillator • Invasive blood pressure measurement • Ext. pelvic stabilisation (belt) • Suprapubic urine drainage system • Emergency medicines • Diagnostic imaging: <ul style="list-style-type: none"> ○ Ultrasound unit, vascular doppler ○ Conventional X-ray diagnostics ○ Alternatively: Mobile X-ray unit ○ CT • Rail and extension systems • Tempering systems <ul style="list-style-type: none"> ○ For patients ○ For infusion and blood • Cell-Saver • Trauma room clock <p>Desirable:</p> <ul style="list-style-type: none"> • Helipad available 24/7 • Diagnostic imaging: <ul style="list-style-type: none"> ○ Angiography workstation with intervention ○ MRI
Equipment for the provision of medical care to the severely injured - operating room	<ul style="list-style-type: none"> • Laparotomy set • Thoracotomy set • Mechanical pelvic stabilisation • Pericardial puncture kit

Intensive care unit	The ability to provide intensive care treatment to a severely injured patient must be maintained (24/7)
Case numbers	<p>Documentation of at least 20 patients who are included in the basic group of patients of the DGU TraumaRegister (M-AIS 3+ / M-AIS 2 patients who died or were treated on the intensive care unit) each year, of which 10 patients with ISS \geq 16</p> <p>→ At re-audit, patient numbers are averaged across the three-year certification interval</p> <p>→ If the case numbers are not achieved on account of a lack of declaration of consent, the following is required:</p> <ul style="list-style-type: none"> ○ Explanation of the method use to collect the declaration of consent ○ Alternative proof of the treated cases
Quality assurance	<ul style="list-style-type: none"> • Protocol for organ donation • “Resuscitation room emergency alert/central group call” SOP • Trauma patient care SOP taking the S3 guidelines into account • Risk management evidence • reporting of the electronic hospital information system • “Screening upon admission and further procedure in case of infections (multi-resistant germs)” SOP • “Avoiding near misses” SOP
Events	<ol style="list-style-type: none"> 1. Participation in network meetings and TraumaNetwork Quality Circle meetings → At least 1x /year → Evidenced by means of certificates of participation 2. Informing all participating doctors and professional groups regarding the results of the DGU TraumaRegister → At least 1x/year 3. Internal Clinic Quality Circle → At least 2x/year → Evidenced by means of minutes 4. Trauma Surgery or Interdisciplinary Morbidity & Mortality Conference → Evidenced by means of minutes
Training, advanced training, and further training of employees	<p>Desirable:</p> <ul style="list-style-type: none"> • Courses on technical competencies: e.g. AO courses, DSTC, Lifelike Fracture Simulation • Courses on procedural competencies: e.g. ATLS, ETC, TDSC • Courses on interpersonal competencies: e.g. Human Factors Training

Mass-casualty incident/mass-casualty terrorist incident exercise	<ul style="list-style-type: none"> • 2 certificates (TDSC/ MRMI or similar) are recommended • Hospital emergency response plan tailored to mass-casualty incidents/mass-casualty terrorist incidents (within the past 3 years) Contents: <ul style="list-style-type: none"> ○ HR concept: Definition of responsible persons - red/yellow/green (decision-makers, persons responsible for visual inspections etc.) ○ Triage concept (incl. room concept and route concept) ○ Emergency alert concept ○ Admission concept (cf. "Admission capacity" tables further below) ○ Security concept (incl. staff access regulations) ○ Equipment concept (incl. emergency surgical instrument sets) → Evidence of: Pelvic C-clamps, non-invasive pelvic stabilisation equipment, tourniquets, haemostyptics, antiseptic solutions) ○ Room concept (identification of treatment areas - red/yellow/green) → Hospital deployment/emergency plan must be in place • Information/training of employees regarding hospital emergency response plan → 1x /3 years → Proof of invitation/agenda • Exercises and emergency simulations → 1x /3 years
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Admission capacities within the first hour for each triage category (TI-TIII):

Service level	TI (red)	TII (yellow)	TIII (green)
Regional TC	1	3	6

Admission capacities after start of emergency plan:

Service level	TI (red)	TII (yellow)	TIII (green)
Regional TC	2	6	12

5. Certification of Supraregional TraumaCentres

White Paper Stipulation	Requirement
Responsible trauma surgery unit (trauma unit)	<ul style="list-style-type: none"> • Department of Orthopaedics/Trauma Surgery → Task: inpatient care for trauma patients • Operational unit with its own (designated) beds • Interdisciplinary ward rounds/meetings on all trauma patients (once a week) → not mandatory ward rounds • Staff composition: <ul style="list-style-type: none"> ▪ Medical management: Orthopaedic Trauma Surgeon/Trauma Surgeon (trauma surgeon must be a stagemeeester) → Mainly responsible for trauma patients from the resuscitation room/operation to discharge, including rehabilitation planning (if necessary) ▪ Deputy management: Orthopaedic Trauma Surgeon/Trauma Surgeon ▪ Other employees (medical staff, nursing staff, etc.)
Organizational chart for the care of severely injured patients	<ul style="list-style-type: none"> • Definition of Trauma Team → Task: Care of the patient in the resuscitation room • Content: <ul style="list-style-type: none"> ○ Presentation of the involved specialties, including attendance and task definitions ○ Regulation of which discipline manages which injuries • At least one surgeon in the leadership team with assigned appropriate responsibilities • Definition of Trauma Leader (preferably a surgeon) with independence in emergency care and ongoing treatment, own personnel resources, own access to operating room capacity, and possibly authority to issue instructions • Clear depiction of the decision-making chain

<p>Basic interdisciplinary team in the resuscitation room (24/7 presence in the hospital)</p>	<ul style="list-style-type: none"> • 1 specialist (or surgeon who provides a standard of care commensurate with the level of a specialist) in orthopaedics/ trauma surgery <i>and</i> • 1 specialist (or surgeon who provides a standard of care commensurate with the level of a specialist) in Emergency medicine (Emergency Physician) → The senior consultant (designated in the service plan) decides on the standard of care commensurate with the level of a specialist <i>or</i> • 1 resident in Emergency medicine (Emergency Physician) • 1 resident in orthopaedics/ trauma surgery <i>or</i> • 1 resident in visceral and/or general surgery • 1 specialist (or physician who provides a standard of care commensurate with the level of a specialist) in anaesthesiology → Specialist must be present with patients in the resuscitation room (written rule must be in place), 24/7 presence in the hospital not essential • 2 emergency department nurses → registered, alternatively registered paramedic • 1 anaesthetic nurse • 1 medical radiology technician <p>→ In addition: Statement explaining how the provision of 2 simultaneous resuscitation room treatments is guaranteed</p>
<p>Extended resuscitation room team (Presence within 30 minutes)</p> <p>All disciplines must be available for every resuscitation room emergency alert</p>	<ul style="list-style-type: none"> • 1 specialist in orthopaedics/ trauma surgery with an additional qualification in special trauma surgery (→ Partner/ Consultant) <i>or</i> • 1 specialist in surgery with a subspecialty qualification in trauma surgery (Partner/ Consultant) • 1 specialist in anaesthesiology (Partner/ Consultant) • 1 specialist in neurosurgery • 1 specialist in radiology with knowledge of interventional radiology • 2 operating room nurses • If applicable, additional on-call services for the simultaneous treatment of 2 severely injured patients <p><u>Additional specialist disciplines:</u></p> <ul style="list-style-type: none"> • 1 specialist in visceral or general surgery (Partner/ Consultant)** • 1 specialist in vascular surgery** • 1 specialist with an additional qualification in hand surgery* • 1 specialist in cardiac and/or thoracic surgery** • 1 specialist in oral and maxillofacial surgery* • 1 specialist in ear, nose and throat medicine

	<ul style="list-style-type: none"> • 1 specialist in ophthalmology* • 1 specialist in urology* • 1 specialist in gynaecology* • 1 specialist in plastic surgery* • 1 specialist in paediatric surgery and/or specialist in paediatrics* <p>→ Disciplines as main specialist departments on site</p> <p>* In exceptional cases, proof of cooperation agreement possible (cf. "Cooperations" section)</p> <p>** In case of differing structures, their equivalence must be verified in the audit.</p>
Main department & cooperations	<ul style="list-style-type: none"> • Definition of main department: at least 3 specialists in full-time positions • In exceptional cases, cooperation is possible for: <ul style="list-style-type: none"> ○ Hand surgery ○ Oral and maxillofacial surgery ○ Ear, nose and throat medicine ○ Ophthalmology ○ Urology ○ Gynaecology ○ Plastic surgery ○ Paediatric surgery or paediatrics <p>→ If no main department in the hospital</p> • Cooperation with another TraumaCenter (preferably RTZ or ÜTZ) → The collaborating hospital must also be recognized as a TraumaCenter and should be certified at least at the same level. • The following content must be regulated: <ul style="list-style-type: none"> ○ Stipulation of the contractual parties ○ Underlying guideline (White Paper in its currently valid edition) ○ Reason for cooperation (identification of the relative specialist department) ○ Definition of the scope of service/contractual object <p><u>Transfer contract:</u></p> <ul style="list-style-type: none"> ▪ Further treatment in another hospital ▪ Necessary structural resources for surgical treatment and intensive medical care must be present within the transfer clinic/hospital ▪ Guarantee of the prompt transfer of the patient, 24/7 (if necessary, a regulation regarding communication if the agreed service cannot be provided in acute cases) ▪ Patient transport time of no more than 30 minutes (form of transport) ▪ Tele-medical cooperation <ul style="list-style-type: none"> ○ Signatures of the managing directors and, if applicable, the clinic/hospital directors

	<ul style="list-style-type: none"> ○ In addition, regulations on the following are also worthwhile: <ul style="list-style-type: none"> ▪ Remuneration and accounting ▪ Termination periods • Furthermore, statutory regulations remain unaffected.
Tailored resuscitation room team	<ul style="list-style-type: none"> • “Tailored resuscitation room team” SOP • To ensure safe patient care, a team must always be available in the resuscitation room that can, as a minimum requirement, run through the resuscitation room algorithm as far as the imaging/diagnostic stage, as such that the patient can be transferred in a stabilised condition from the “Primary Survey” in accordance with ATLS® for further treatment At least the following composition: <ul style="list-style-type: none"> ○ 1 specialist in orthopaedics/ trauma surgery (or surgeon who provides a standard of care commensurate with the level of a specialist) ○ 1 specialist in surgery in emergency medicine (Emergency physician) (or surgeon who provides a standard of care commensurate with the level of a specialist) ○ 1 specialist in anaesthesiology (or physician who provides a standard of care commensurate with the level of a specialist) ○ 1 emergency department nurse → registered, alternatively registered paramedic ○ 1 anaesthetic nurse ○ 1 medical radiology technician
Training in the medical care of the severely injured	<ul style="list-style-type: none"> • Valid ATLS certificates must be verified for all trauma specialists and emergency physicians deployed in the resuscitation room → In addition, for all other doctors deployed in the resuscitation room (First service and partner/ consultant), an ATLS certificate is recommended • Equivalent: ETC certificate (valid for 5 years)
Emergency department trauma unit	<ul style="list-style-type: none"> • Resuscitation room for 2 patients spanning at least 50 m² → Alternatively, 2 resuscitation rooms, each spanning 25 m² • X-ray equipment must be available in the resuscitation room → Not necessary if CT is in an adjacent room (on the same level, in direct proximity) • CT in the resuscitation room or an adjacent room → maximum distance of 50 m • In case of new construction/renovation planning: CT in the resuscitation room or adjoining room • An operating theatre is not required in the resuscitation room

Equipment for the treatment of the severely injured - Emergency department	<ul style="list-style-type: none"> • Blood donation service or blood depot • Laboratory → Results must be available 24/7 • Microbiology • Ventilator • Pulse oximetry system • Extraction system • Capnography system • Video laryngoscope • Bronchoscopy • Pleural drainage • Blood gas analyser (BGA unit) → Located in emergency department! • Fast infusion system • ECG monitor • Defibrillator • Invasive blood pressure measurement • Ext. pelvic stabilisation (belt) • Suprapubic urine drainage system • Emergency medicines • Diagnostic imaging: <ul style="list-style-type: none"> ○ Ultrasound unit, vascular doppler ○ Conventional X-ray diagnostics Alternatively: Mobile X-ray unit ○ CT ○ Angiography workstation with intervention ○ MRI • Rail and extension systems • Tempering systems <ul style="list-style-type: none"> ○ For patients ○ For infusion and blood • Cell-Saver • Resuscitation room clock <p>Desirable:</p> <ul style="list-style-type: none"> • Helipad available 24/7 → (PIS approval sufficient)
Equipment for the provision of medical care to the severely injured - operating room	<ul style="list-style-type: none"> • Laparotomy set • Thoracotomy set • Mechanical pelvic stabilisation • Craniotomy • Pericardial puncture kit
Intensive care unit	<p>The ability to provide intensive care treatment to two severely injured patients in parallel must be maintained (24/7).</p>

Case numbers	<p>Documentation of at least 40 patients who are included in the basic group of patients of the DGU TraumaRegister (M-AIS 3+ / M-AIS 2 patients who died or were treated on the intensive care unit) each year, of which 40 patients with ISS \geq 16</p> <p>→ At re-audit, patient numbers are averaged across the three-year certification interval</p> <p>→ If the case numbers are not achieved on account of a lack of declaration of consent, the following is required:</p> <ul style="list-style-type: none"> ○ Explanation of the method use to collect the declaration of consent ○ Alternative proof of the treated cases
Quality assurance	<ul style="list-style-type: none"> • Protocol for organ donation • “Resuscitation room emergency alert/central group call” SOP • Tailored resuscitation room SOP (if used) • Medical Care of the Severely Injured SOP taking the S3 guidelines into account • Risk management evidence • reporting of the electronic hospital information system • “Screening upon admission and further procedure in case of infections (multi-resistant germs)” SOP • “Avoiding near misses” SOP
Events	<ol style="list-style-type: none"> 1. Participation in network meetings and Trauma Network Quality Circle meetings → At least 1x /year → Evidenced by means of certificates of participation 2. Informing all participating doctors and professional groups regarding the results of the DGU Trauma Register → At least 1x /year 3. Internal Clinic Quality Circle → At least 2x /year → Evidenced by means of minutes 4. Trauma Surgery or Interdisciplinary Morbidity & Mortality Conference → Evidenced by means of minutes
Training, advanced training, and further training of employees	<p>Desirable:</p> <ul style="list-style-type: none"> • Courses on technical competencies: e.g. AO courses, DSTC, Lifelike Fracture Simulation • Courses on procedural competencies: e.g. ATLS, ETC, TDSC • Courses on interpersonal competencies: e.g. Human Factors Training

Mass-casualty incident/mass-casualty terrorist incident exercise	<ul style="list-style-type: none"> • 2 certificates (TDSC/ MRMI or similar) are recommended • Hospital emergency response plan tailored to mass-casualty incidents/mass-casualty terrorist incidents (within the past 3 years) Contents: <ul style="list-style-type: none"> ○ HR concept: Definition of responsible persons - red/yellow/green (decision-makers, persons responsible for triage, etc.) ○ Triage concept (incl. room concept and route concept) ○ Emergency alert concept ○ Admission concept (cf. "Admission capacity" tables further below) ○ Security concept (incl. staff access regulations) ○ Equipment concept (incl. emergency surgical instrument sets) → Evidence of: Pelvic C-clamps, non-invasive pelvic stabilisation equipment, tourniquets, haemostatics, antiseptic solutions ○ Room concept (identification of treatment areas - red/yellow/green) <p>→ Hospital emergency response plan must be in place</p> <ul style="list-style-type: none"> • Information/training of employees regarding hospital emergency response plan → 1x /3 years → Proof of invitation/agenda • Exercises and emergency simulations → 1x /3 years
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Admission capacities within the first hour for each triage category (TI-TIII):

Service level	TI (red)	TII (yellow)	TIII (green)
Supraregional TC	2	5	3

Admission capacities after start of emergency plan:

Service level	TI (red)	TII (yellow)	TIII (green)
Supra-regional TC	4	10	6