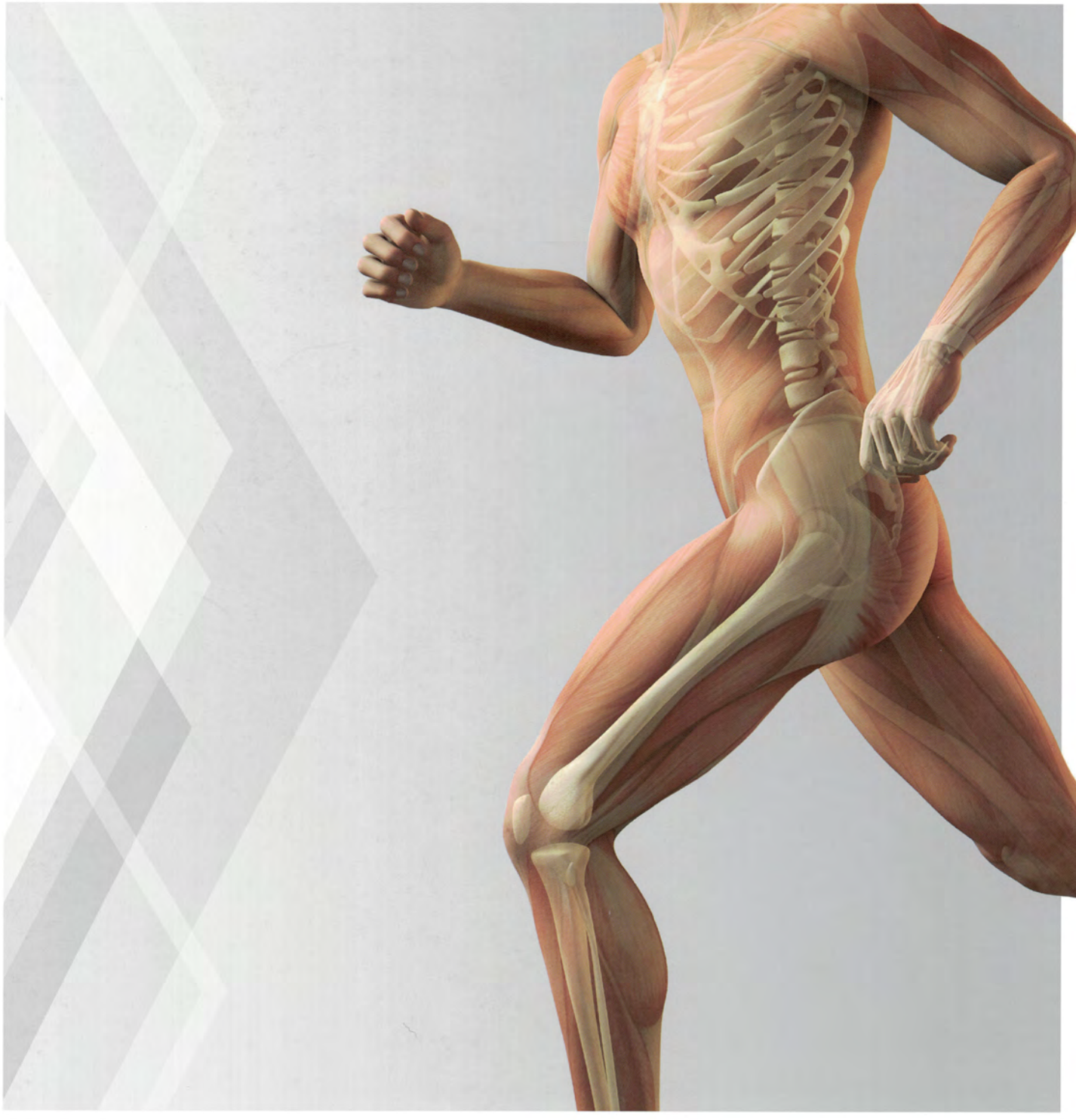
DIZG

DEUTSCHES INSTITUT FÜR
ZELL- UND GEWEBEERSATZ

Gemeinnützige Gesellschaft mbH

Transplants for sports medicine



DIZG
Safety and quality

The German Institute for Cell and Tissue Replacement (DIZG) was founded as a non-profit institution in 1993 by physicians and scientists from the University of Erlangen and the tissue banks of the University of Leipzig and the Charité Hospital in Berlin and is based on their vast experience. DIZG aims to make the best possible use of charitably donated tissue in order to enhance the perspectives of healing for patients with serious defects.

Therefore DZIG supports tissue donation, conducts research and is continuously developing its range of tissue transplants. To date, the non-profit institute has supplied over 400,000 human tissue transplants to surgeons and hospitals worldwide. At present, more than 37,000 patients with severe injuries benefit from around 350 different transplant types from the DIZG cleanrooms each year.

Patients and physicians are guaranteed the highest levels of quality and safety, since in Germany, tissue transplants of human origin are regulated as medicinal products and subject to marketing authorisation. The manufacture, biological safety and clinical application of these so-called "allografts" are subject to surveillance by the German authorities. The DIZG holds eleven marketing authorisations for groups of human tissue transplants.

The transplants are produced in Class A cleanrooms by DIZG in Berlin, in compliance with Good Manufacturing Practice (GMP) requirements. The DIZG has established a comprehensive quality system to guarantee the biological safety of the tissue transplants. Donors are selected based on strict criteria. Serological screening exceeds the EU Directive 2006/17 specifications and among other elements, includes three viral genome tests. Furthermore, a validated process for virus inactivation and elimination of bacteria and fungi, as well as in-process and final inspections of the transplants, ensure compliance with the highest safety requirements.

DIZG is also certified according to DIN EN ISO 9001 and adheres to the Ethical Code and quality standards of the European Association of Tissue Banks (EATB).

All this contributes towards supplying a growing number of patients with safe and high-quality human tissue transplants.

Contents

Knee
Rupture of the cruciate ligament

Ruptured cruciate ligaments are preferably reconstructed with autologous tendons. Use of an allogenic tendon can be the means of choice in case of repeated injury or if an autologous tendon cannot or should not be removed. The tendons listed on the facing page are suitable for the replacement of the anterior and posterior cruciate ligament.

The following applies to all tendons:

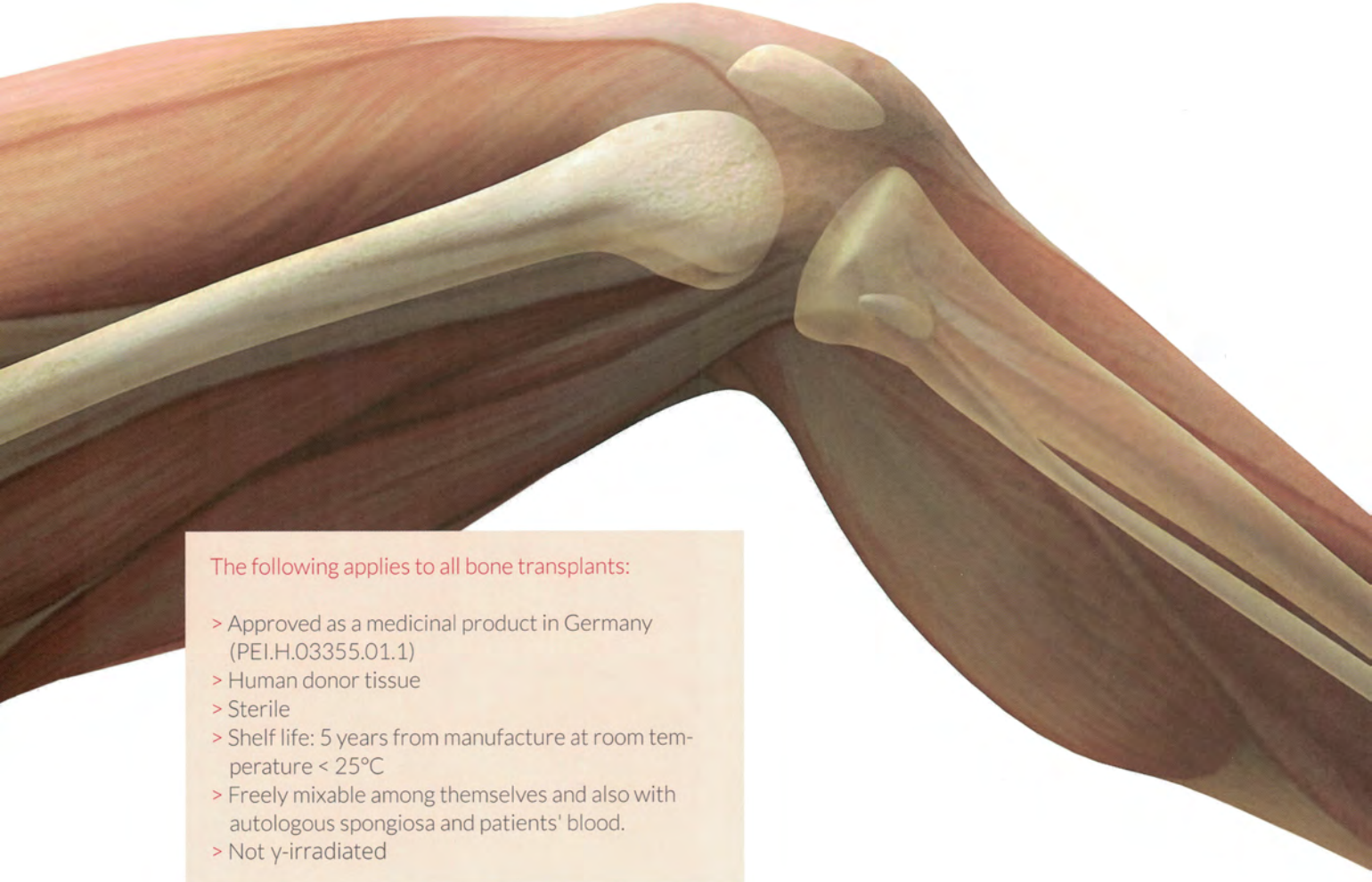
- Approved as a medicinal product in Germany (PEI.H.03356.01.1)
- Human donor tissue
- Sterile
- Frozen
- Shelf life: 2 years if not stored above -40°C
- Supplied on dry ice together with a quantity of dry ice that guarantees adequate cooling for 24h
- Not γ-irradiated

TRANSPLANT	PROPERTIES	ORDER NUMBER
Semitendinosus tendon 	≥ 26 cm < 26 cm	TK3107 TK3108
Gracilis tendon 	≥ 20 cm	TK3109
Tibialis tendon, anterior 	≥ 22 cm	T K3110
Tibialis tendon, posterior 	≥ 22 cm	T K3111
Peroneus longus tendon	≥ 22 cm	TK3112

Tendon specifications, see pages 14/15

Knee
Drill tunnel filling

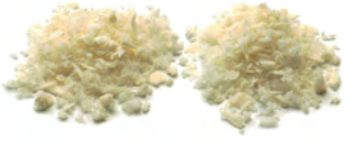
Malpositioned drill tunnels must often be filled in revision cruciate ligament surgery. Allogenic bone transplants are ideal in these cases as a new, stable boney substrate is formed over a period of about four to six months and a new tunnel can be drilled. The freeze-dried transplants must be rehydrated in sterile physiological saline solution for 30 minutes prior to use in surgery.



The following applies to all bone transplants:

- Approved as a medicinal product in Germany (PEI.H.03355.01.1)
- Human donor tissue
- Sterile
- Shelf life: 5 years from manufacture at room temperature < 25°C
- Freely mixable among themselves and also with autologous spongiosa and patients' blood.
- Not γ-irradiated

Supplied in freeze-dried condition – rehydration in sterile physiological saline solution for 30 minutes prior to use.

TRANSPLANT	PROPERTIES	ORDER NUMBER
Spongiosa, crushed		
	> 5 cm^3	GT2850
	> 10 cm^3	GT2851
	> 15 cm^3	GT2852
Spierings chips	Milled from pelvic bone using a Spierings bone mill; a mixture of cancellous and cortical bone, various pack sizes and grains	
	Spierings chips, fine (up to 8 mm)	
	> 10 cm^3	GT2756
	> 15 cm^3	GT2757
	> 30 cm^3	GT2758
	Spierings chips, coarse (up to 10 mm)	
	> 10 cm^3	GT2748
	> 15 cm^3	GT2749
	> 30 cm^3	GT2753
Spongiosa cylinder	Manufactured from pure spongiosa	
	Diameter 10 mm Length up to 30 mm	GT2606
	Diameter 12 mm Length up to 30 mm	GT2610

Shoulder

Rotator cuff repair
Acromioclavicular joint stabilisation

epiflex® is produced from donated human dermis. The collagen structure is largely preserved due to the tissue-conserving manufacturing process. epiflex® is cell-free. No immune reactions have been observed. epiflex® serves as a scaffold for revascularisation and cell colonisation.

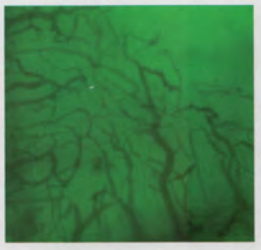
The following applies to epiflex®:

- Approved as a medicinal product in Germany (3003749.00.00)
- Human donor skin tissue
- Sterile
- Shelf life: 5 years from manufacture at room temperature < 25°C
- Supplied in freeze-dried condition – rehydration in sterile physiological saline solution for 30 minutes prior to use
- Not γ-irradiated

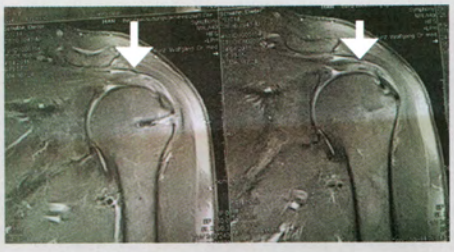
The following applies to all tendons:

- Approved as a medicinal product in Germany (PEI.H.03356.01.1)
- Human donor tissue
- Sterile
- Frozen
- Shelf life: 2 years if not stored above -40°C
- Supplied on dry ice together with a quantity of dry ice that guarantees adequate cooling for 24h
- Not γ-irradiated

TRANSPLANT	PROPERTIES	ORDER NUMBER
epiflex®	> Various sizes/ tensile strengths:	> 0.8 mm
	3 x 3 cm (F_{max}: 1,042 N)*	GT4060
	4 x 4 cm (F_{max}: 1,390 N)*	GT4061
	2 x 16 cm (F_{max}: 695 N)*	GT4059
	> Highly flexible	
	> Highly resilient	
	> E-modulus: 90 MPa	
	> Suture tear strength: 96 N (1 loop, suture strength USP 2-0)	
	* F_{max}: depending on cross-section	
	Ideal matrix for cell migration and vascularisation	
Semitendinosus tendon	< 26 cm Acromioclavicular joint stabilisation	TK3108



In vivo neo-angiogenesis in rats

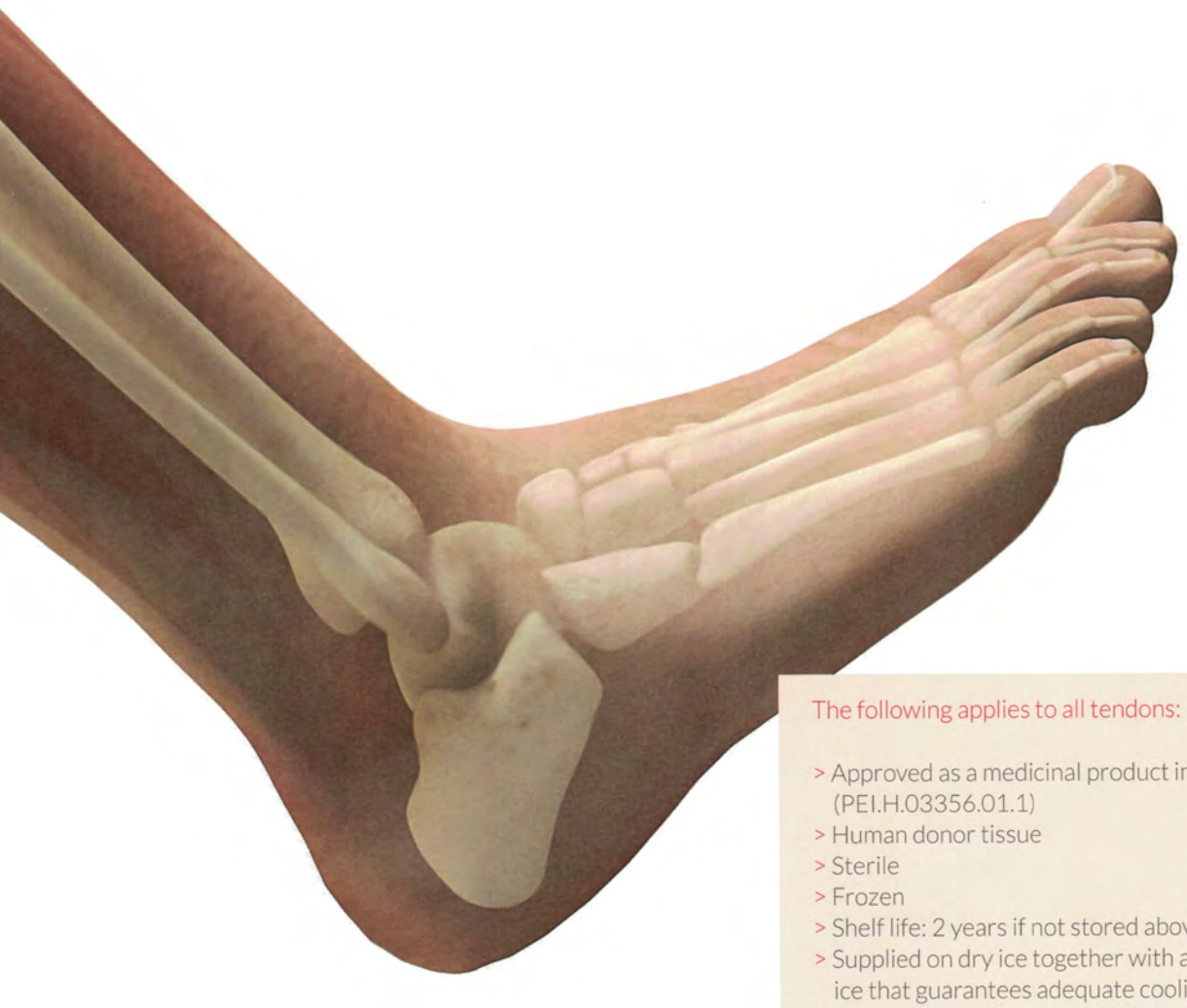


MRT image, epiflex® is largely integrated 7 months postoperatively – the transition tendon/epiflex® is only outlined marginally.

Foot

Rupture of the Achilles tendon
Injuries of other ligaments and tendons

Allogenic tendon transplants are suitable as replacements for injured tendons and ligaments.



The following applies to all tendons:

- Approved as a medicinal product in Germany (PEI.H.03356.01.1)
- Human donor tissue
- Sterile
- Frozen
- Shelf life: 2 years if not stored above -40°C
- Supplied on dry ice together with a quantity of dry ice that guarantees adequate cooling for 24h
- Not γ-irradiated

TRANSPLANT	PROPERTIES	ORDER NUMBER
Semitendinosus tendon 	≥ 26 cm < 26 cm	TK3107 TK3108
Gracilis tendon 	≥ 20 cm	TK3109
Tibialis tendon, anterior 	≥ 22 cm	T K3110
Tibialis tendon, posterior 	≥ 22 cm	T K3111
Peroneus longus tendon	≥ 22 cm	TK3112

Elbow & lateral ligaments
Injuries of ligament structures and elbow tendons

epiflex® is produced from donated human dermis. The collagen structure is largely preserved due to the tissue-conserving manufacturing process. epiflex® is cell-free. No immune reactions have been observed. epiflex® serves as a scaffold for revascularisation and cell colonisation. epiflex® is suitable for augmentation in injuries of ligament structures.

Allogenic tendons are suitable as replacements for injured ligaments.

The following applies to epiflex®:

> Approved as a medicinal product in Germany (3003749.00.00)
> Human donor skin tissue
> Sterile
> Shelf life: 5 years from manufacture at room temperature < 25°C
> Supplied in freeze-dried condition – rehydration in sterile physiological saline solution for 30 minutes prior to use
> Not γ-irradiated

The following applies to all tendons:

> Approved as a medicinal product in Germany (PEI.H.03356.01.1)
> Human donor tissue
> Sterile
> Frozen
> Shelf life: 2 years if not stored above -40°C
> Supplied on dry ice together with a quantity of dry ice that guarantees adequate cooling for 24h
> Not γ-irradiated

TRANSPLANT	PROPERTIES	ORDER NUMBER
epiflex®	> Various sizes/tensile strengths:	> 0.8 mm
	3 x 3 cm (F_{max}: 1,042 N)*	GT4060
	4 x 4 cm (F_{max}: 1,390 N)*	GT4061
	5 x 5 cm (F_{max}: 1,737 N)*	GT4065
	2 x 4 cm (F_{max}: 695 N)*	GT4057
	2 x 8 cm (F_{max}: 695 N)*	GT4058
	2 x 16 cm (F_{max}: 695 N)*	GT4059
	4 x 16 cm (F_{max}: 1,390 N)*	GT4064
	> Highly flexible	
	> Highly resilient	
	> E-modulus: 90 MPa	
	> Suture tear strength: 96 N (1 loop, suture strength USP 2-0)	
	* F_{max}: depending on cross-section	
Gracilis tendon	≥ 20 cm	TK3109

Tendon specifications

To provide an optimal choice of tendon transplants, DIZG can supply the following dimensions:

Semitendinosus, tibialis, gracilis and peroneus longus tendons

L = length
W = width

Folded diameter for semitendinosus, tibialis and gracilis tendons and peroneus longus tendon

If required, please request our current daily list with the dimensions of the available tendons per email: distribution@dizg.de or by telephone on +49 30 577 07 80 60

Information

GENERAL INFORMATION

The use of DIZG transplants must be fully documented in accordance with the German transplant law. Labels for patient files are included in every package for this purpose.

Explanations and notes about the clinical application of the transplants are detailed in the instructions for use and information for specialists found in every package.

TRANSPORT

In principle, all requests for delivery at specific times can be met. The costs incurred by DIZG will be charged in full.

PRESERVATION METHODS

Freeze-drying (GT)
The transplants designated with a GT are freeze-dried and are stable for five years from the date of manufacture, when stored in unopened packaging at or below 25 °C. All freeze-dried transplants listed here must be rehydrated in a suitable sterile physiological medium (e. g. isotonic infusion solution, patient's blood) for at least 30 minutes.

Deep-freezing (TK)
All transplants designated with a TK are preserved deep-frozen. When stored in unopened packaging at below -40 °C, the shelf life is two years from the date of manufacture. Deep-frozen preparations are to be thawed prior to use in a suitable sterile, physiological medium (e.g. isotonic infusion solution, patient's blood).

ORDERS

You can download the order form as PDF from our website and fill it out at your convenience.
www.dizg.de/gewebetransplantate/pdf-downloads/fomulare

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