



DIZG



TRANSPLANTS FOR SPORTS MEDICINE

www.dizg.de

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 Universities of Erlangen and Leipzig and the Charité University Hospital in Berlin, thus embracing the traditions and vast experience of the tissue banks from Leipzig University and the Charité.

DIZG aims to make the best possible use of charitably donated tissue in order to enhance the perspectives of patients with serious tissue defects. Therefore, DIZG supports tissue donation and 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. Presently, 30,000 patients with severe injuries benefit each year from transplants manufactured by DIZG. Eleven medicinal product marketing authorizations provide the basis of a transplant catalog with more than 250 transplant variants.

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 human tissue transplants are subject to surveillance by the German authorities. The transplants are produced in Class A clean rooms in Berlin, in compliance with Good Manufacturing Practice (GMP) requirements.

A comprehensive quality system guarantees 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 is applied to all transplants. In-process controls and batch release tests including pharmacopoeia compliant sterility testing complete an extensive system of quality control measures that meet the strictest safety requirements.

DIZG is certified according to DIN EN ISO 13485 and 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, high-quality human tissue transplants.

TABLE OF CONTENTS

KNEE

| | |
|--------------------------------|----|
| Cruciate ligament repair | 04 |
| Drill tunnel filling | 06 |

SHOULDER

| | |
|--|----|
| Rotator cuff repair; Acromioclavicular stabilization | 08 |
|--|----|

FOOT

| | |
|--|----|
| Achilles tendon repair; Repair of other tendons/ligaments..... | 10 |
|--|----|

ELBOW & LATERAL LIGAMENTS

| | |
|--|----|
| Elbow tendon repair; Lateral ligament repair | 12 |
|--|----|

INFORMATION

| | |
|--|----|
| Tendon/Ligament specifications | 14 |
| General information and ordering | 15 |

KNEE







CRUCIATE LIGAMENT REPAIR

Ruptured cruciate ligaments are preferably reconstructed with autologous tendons. Use of an allogenic tendon can be appropriate in cases 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:

- Manufactured and distributed under a marketing authorisation as a medicinal product in Germany (PEI.H.03355.01.1)
- Human donor tissue
- Sterile
- Frozen
- Shelf life: 2 years at -40°C
- Supplied with a quantity of dry ice that guarantees adequate cooling for 24h

| TRANSPLANT* | PROPERTIES | ORDER NUMBER |
|---|---|---|
| Semitendinosus tendon | ≥ 26 cm | TK3107 |
| | < 26 cm | TK3108 |
|  | | |
| Gracilis tendon | ≥ 20 cm | TK3109 |
|  | | |
| Tibialis tendon, anterior | ≥ 20 cm | TK3110 |
|  | | |
| Tibialis tendon, posterior | ≥ 22 cm | TK3111 |
|  | | |
| Patellar tendon (BTB) | <p>Patellar tendons are supplied either complete or halved</p> <ul style="list-style-type: none"> ▪ Complete, with bone blocks ▪ Halved, with bone blocks ▪ Complete, with bone blocks and quadriceps tendon ▪ Halved, with bone blocks and quadriceps tendon | <p>TK3601</p> <p>TK3602</p> <p>TK3603</p> <p>TK3604</p> |
|  | | |
| Patellar tendon, pre-shaped | <p>The diameter of the bone blocks is approx. 10 mm.</p> <p>The patellar tendons with pre-shaped bone blocks are produced from the halved patellar tendon</p> | TK3605 |
|  | | |

*Tendon specifications, see page 14/15

KNEE

DRILL TUNNEL FILLING




Pre-existing drill tunnels must often be filled in revision cruciate ligament reconstruction. Allogenic bone transplants can be used to fill such tunnels. Over a period of about four to six months a new, stable boney substrate is formed and a new tunnel can be drilled.

Freeze-dried bone transplants must be rehydrated in sterile physiological saline for 30 minutes prior to use.



The following applies to all cancellous bone transplants:

- Manufactured and distributed under a marketing authorisation as a medicinal product in Germany (PEI.H.03356.01.1)
- Human donor tissue
- Sterile
- Freeze-dried
- Shelf life: 5 years at room temperature (<25°C)

| TRANSPLANT | PROPERTIES | ORDER NUMBER |
|--|--|--|
| Cancellous chips  | < 1cm Package sizes: <ul style="list-style-type: none"> ▪ 5 cm³ ▪ 10 cm³ ▪ 15 cm³ ▪ 20 cm³ ▪ 30 cm³ | GT2801 GT2802 GT2804 GT2805 GT2803 |
| Spierings chips  | Milled from pelvic bone using a Spierings bone mill; a mixture of cancellous and cortical bone. Package and grain sizes: Fine (up to 8 mm) <ul style="list-style-type: none"> ▪ 10 cm³ ▪ 15 cm³ ▪ 30 cm³ ▪ 45 cm³ ▪ 60 cm³ Coarse (up to 10 mm) <ul style="list-style-type: none"> ▪ 10 cm³ ▪ 15 cm³ ▪ 30 cm³ ▪ 45 cm³ ▪ 60 cm³ | GT2756 GT2757 GT2758 GT2759 GT2760 GT2748 GT2749 GT2753 GT2754 GT2755 |
| Cancellous cylinders (dowels)  | Produced from cancellous bone Diameter 10 mm Length approx. 30 mm | GT2606 |

SHOULDER

ROTATOR CUFF REPAIR ACROMIOCLAVICULAR JOINT STABILIZATION

epiflex® is produced from donated human dermis. The native collagen structure is largely preserved. epiflex® is cell-free. No immune reactions have been observed. epiflex® serves as a scaffold for revascularization and cell colonization.

Allogenic tendons are suitable replacements for the reconstruction of the acromioclavicular joint.

The following applies to epiflex®:

- Manufactured and distributed under a marketing authorisation as a medicinal product in Germany (3003749.00.00)
- Human donor skin tissue
- Sterile
- Freeze-dried
- Shelf life 5 years at room temperature (<25°C)
- Must be rehydrated in sterile physiological saline for 30 minutes prior to use

The following applies to all tendons:

- Manufactured and distributed under a marketing authorisation as a medicinal product in Germany (PEI.H.03355.01.1)
- Human donor tissue
- Sterile
- Frozen
- Shelf life: 2 years at -40°C
- Supplied with a quantity of dry ice that guarantees adequate cooling for 24h



SHOULDER

TRANSPLANT

PROPERTIES

ORDER NUMBER

epiflex®



- Package sizes:
 - 3 x 3 cm
 - 4 x 4 cm
 - 5 x 5 cm
- Highly flexible
- Mechanical strength:
 - Ultimate load: 70 N
 - Young's modulus: 15 MPa
 - Suture tear-out strength: > 3 MPa

| | |
|--------------|----------|
| 0.3 – 0.8 mm | > 0.8 mm |
| GT4010 | GT4060 |
| GT4011 | GT4061 |
| GT4015 | GT4065 |

Ideal matrix for cell migration and vascularisation



In vivo neoangiogenesis in rats

Semitendinosus tendon

< 26 cm
For acromioclavicular joint stabilisation

TK3108



FOOT

ACHILLES TENDON REPAIR REPAIR OF OTHER TENDONS / LIGAMENTS






Allogenic tendon transplants can be appropriate for the repair of ruptured tendons and ligaments of the foot and ankle joint.



The following applies to all tendons:

- Manufactured and distributed under a marketing authorisation as a medicinal product in Germany (PEI.H.03356.01.1)
- Human donor tissue
- Sterile
- Shelf life: 2 years at -40°C
- Supplied with a quantity of dry ice that guarantees adequate cooling for 24h

FOOT

| TRANSPLANT | PROPERTIES | ORDER NUMBER |
|---|--|--------------|
| <p>Achilles tendon with calcaneus</p>  | Complete, < 15 cm | TK3102 |
| | Complete, \geq 15 cm | TK3103 |
| | Halved, < 15 cm | TK3105 |
| | Halved, \geq 15 cm | TK3106 |
| | Achilles tendon w/o calcaneus, complete | TK3101 |
| <p>Semitendinosus tendon</p>  | \geq 26 cm | TK3107 |
| | < 26 cm | TK3108 |
| <p>Gracilis tendon</p>  | \geq 20 cm | TK3107 |
| <p>Tibialis tendon</p>  | Tibialis tendon, anterior \geq 20 cm | TK3110 |
| | Tibialis tendon, posterior \geq 22 cm | TK3111 |
| <p>Quadriceps tendon</p>  | With patellar bone block | TK3606 |

ELBOW & LATERAL LIGAMENTS

ELBOW TENDON REPAIR LATERAL LIGAMENT REPAIR

epiflex® is produced from donated human dermis. The native collagen structure is largely preserved. epiflex® is cell-free. No immune reactions have been observed. epiflex® serves as a scaffold for revascularization and cell colonization.

Allogenic tendons are suitable replacements for the reconstruction of the acromioclavicular joint.

The following applies to epiflex®:

- Manufactured and distributed under a marketing authorisation as a medicinal product in Germany (3003749.00.00)
- Human donor skin tissue
- Sterile
- Freeze-dried
- Shelf life 5 years at room temperature (<25°C)
- Must be rehydrated in sterile physiological saline for 30 minutes prior to use

The following applies to all tendons:

- Manufactured and distributed under a marketing authorisation as a medicinal product in Germany (PEI.H.03355.01.1)
- Human donor tissue
- Sterile
- Frozen
- Shelf life: 2 years at -40°C
- Supplied with a quantity of dry ice that guarantees adequate cooling for 24h



ELBOW & LATERAL LIGAMENTS

TRANSPLANT

PROPERTIES

ORDER NUMBER

epiflex®



▪ Package sizes:

3 x 3 cm

4 x 4 cm

5 x 5 cm

2 x 4 cm

2 x 8 cm

▪ Highly flexible

▪ Mechanical strength:

▪ Ultimate load: 70N

▪ Young's modulus: 15MPa

▪ Suture tear-out resistance: > 3MPa

> 0.8mm

GT4060

GT4061

GT4065

GT4057

GT4058

Gracilis tendon

≥20cm

TK3109



TENDON / LIGAMENT SPECIFICATIONS

The following dimensions are provided for transplants selection guidance:

Semitendinosus, tibialis and gracilis tendons

L = length

W = width

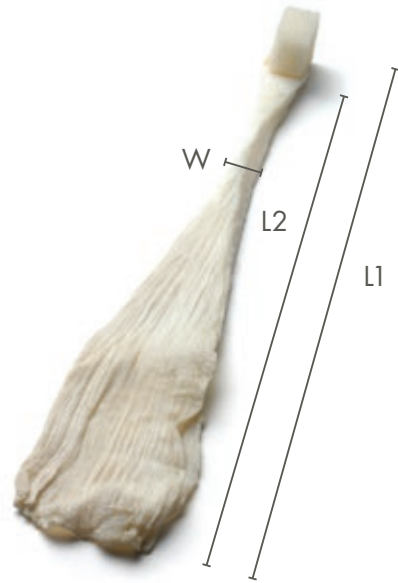


Achilles tendons

L1 = total length incl. bone block

L2 = length of tendon portion

W = width of tendon portion



Folded diameter for semitendinosus, tibialis and gracilis tendons

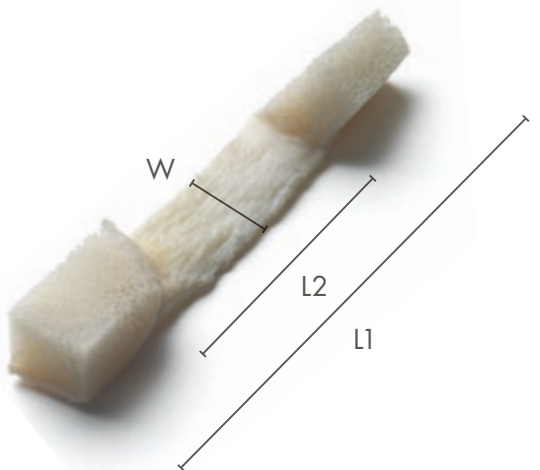


Patellar tendons (BTB)

L1 = total length incl. bone blocks

L2 = length of tendon portion

W = width of tendon portion



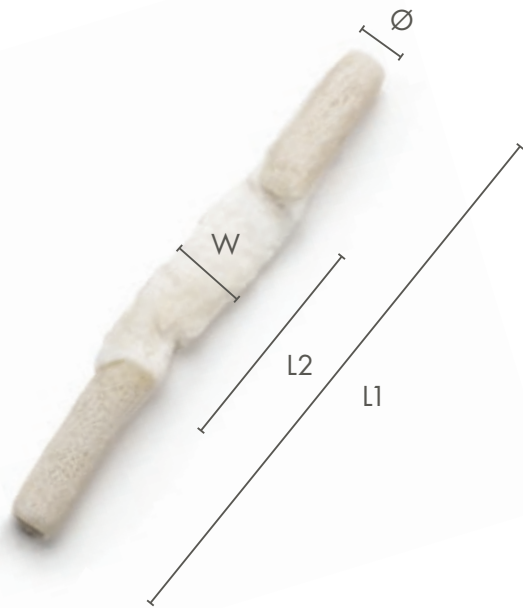
Patellar tendons, pre-shaped

L1 = total length incl. bone blocks

L2 = length of tendon portion

W = width of tendon portion

Ø = diameter of bone block



Quadriceps tendons with bone block

L1 = total length incl. bone block

L2 = length of tendon portion

W = width of tendon portion



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

GENERAL INFORMATION

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

All dimensions are approximate and/or minimum values. This is a result of inter-donor variance.

Advice about the clinical application of the transplants is detailed in the "Instructions for use" leaflet found in every package.

TRANSPORT

In principle, requests for delivery at specific times can be met. All additional costs arising will be charged.

PRESERVATION METHODS

FREEZE-DRYING (GT)

The transplants designated with a GT catalogue number are freeze-dried. Freeze-dried transplants are stable for 5 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 physiological medium (e.g. isotonic saline) for at least 30 minutes.

FREEZING (TK)

All transplants designated with a TK catalogue number are frozen. These transplants are stable for 2 years from the date of manufacture providing they are stored unopened in their packaging, at or below -40°C. Prior to application, frozen transplants should be thawed in a suitable physiological medium (e.g. isotonic saline).

ORDERS

A pdf order form can be downloaded from our website:

www.dizg.de/de/gewebetplantate/pdf-download/formulare



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