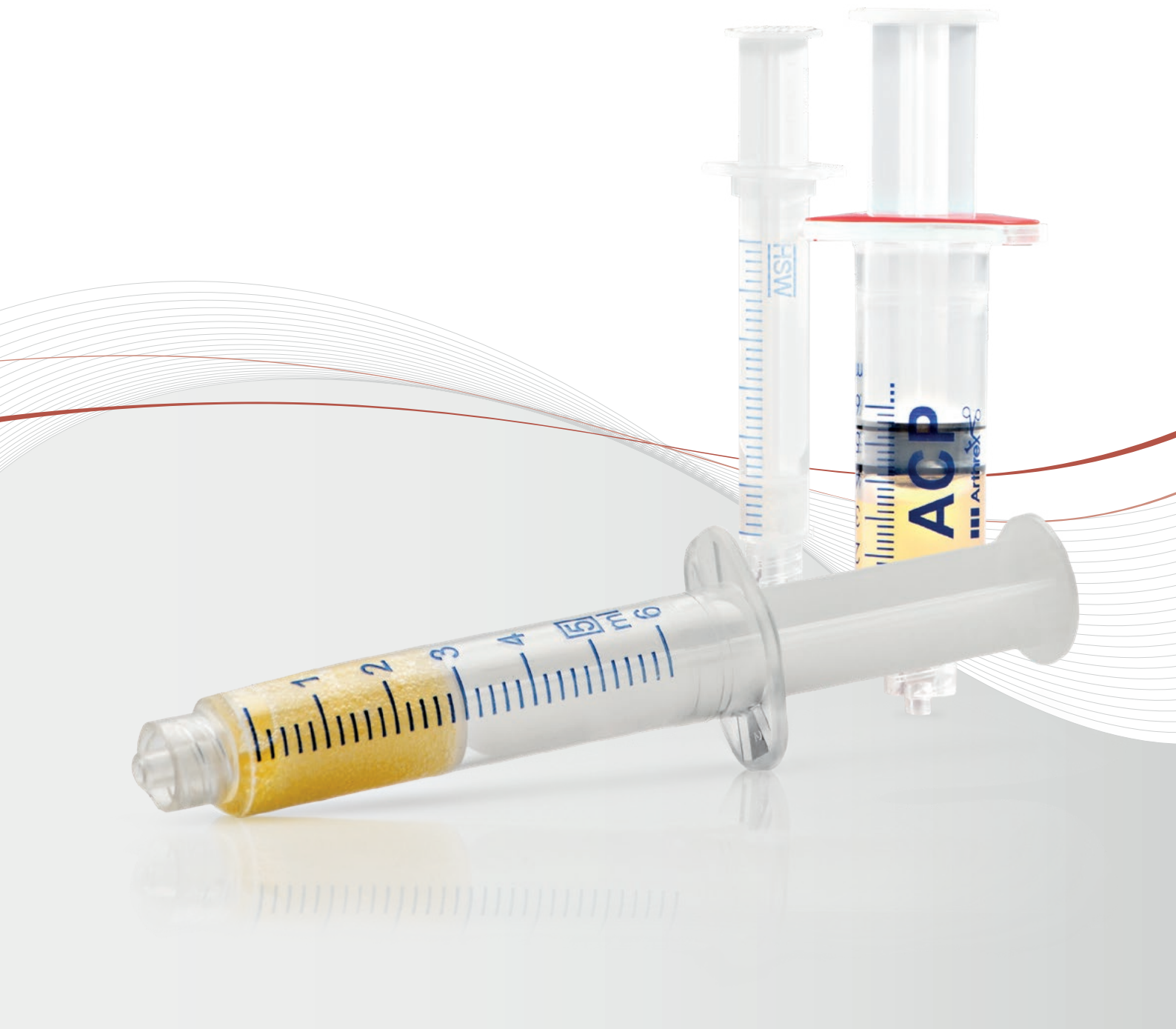


# Arthrex ACP<sup>®</sup> Tendo

The Next Generation Treatment for Tendinopathies



# Arthrex ACP® Tendo

The Next Generation Treatment for Tendinopathies

## Principle of Arthrex ACP® Tendo



### Introduction

Arthrex ACP Tendo provides a novel, patient-friendly and easy-to-use treatment for tendinopathies. It combines the advantages of autologous conditioned plasma (ACP) with the benefits of an innovative scaffold material, VergenixSTR, based on recombinant human collagen (rhCollagen). The interaction of ACP with the rhCollagen matrix creates a growth factor depot, enabling a prolonged release of growth factors to the injury site for up to four weeks, and can promote hemostasis, tissue renewal, and regeneration.

### Indications

Arthrex ACP Tendo is intended for use in the treatment of tendinopathies, e.g., epicondylitis, patellar tendinopathy, plantar fasciitis.

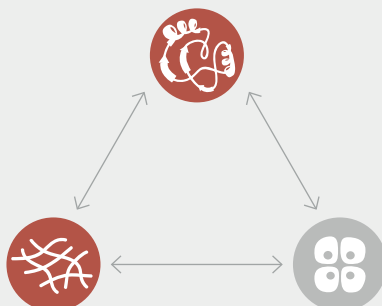
### Features and Benefits

- Innovative technology – VergenixSTR rhCollagen brings advantages to tissue-extracted collagen
- Growth factor depot – elevated levels of growth factors for a prolonged time
- Single injection – less pain for the patient

### Arthrex ACP® Healing Triad

The Arthrex ACP healing triad comprises the cornerstones required for healing: “growth factors”, “matrix”, and “regenerative cells”.

Arthrex ACP Tendo covers the **growth factor** and **matrix** aspects.



-  Growth factors
-  Matrix
-  Regenerative cells

## Mode of Action

The application of Arthrex ACP Tendo to the injury site can accelerate a tissue repair cascade that is characterized by the following processes:

### 1. Interaction of ACP and Vergenix™STR

- Formation of fibrin-rhCollagen matrix entrapping the platelets for clot formation

### 2. Growth Factor Release at Injury Site

- Elevated levels of growth factors for a prolonged time
- Attenuation of inflammatory signals
- Recruitment of cells necessary for healing and neovascularization

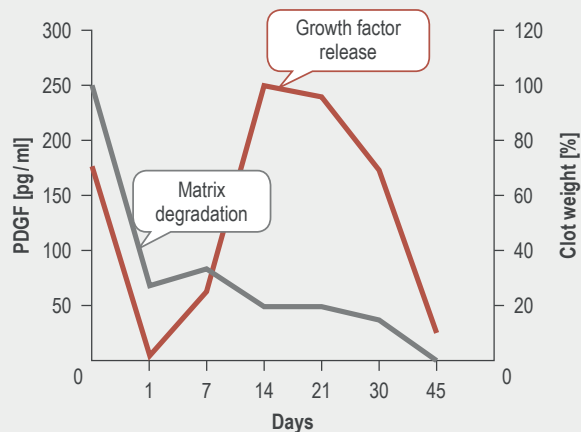
### 3. Scaffold for Tendon Healing

- Adhesion and proliferation of cells needed for tendon healing
- Natural extracellular matrix is formed
- Proliferation and alignment of fibroblasts results in faster maturation and less scar tissue

### 4. Biodegradation and Replacement of Vergenix™STR

- Complete maturation of fibrotic tissue
- Arrest of the inflammation process

## Growth Factor Release



Time course of growth factor release in an animal model. Rats were treated with a subcutaneous injection of VergenixSTR/PRP (platelet-rich plasma) and growth factor content was measured by ELISA at different time points over the course of several weeks. Clot degradation was measured by clot weight.

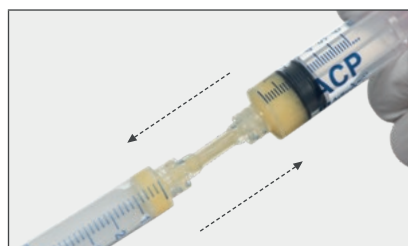
■ Matrix/clot weight (STR/PRP)  
■ PDGF content

## Preparation and Application

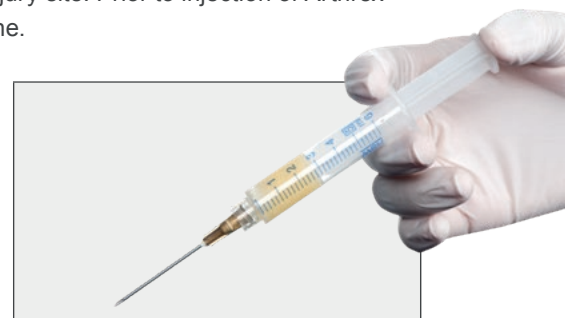
ACP is obtained from the patient's blood using the Arthrex ACP double-syringe system. This is then easily combined with the lyophilized collagen via a syringe adapter. After homogenizing, Arthrex ACP Tendo (approximately 3 ml) can be injected using a 19G needle, initiating clot formation in the vicinity of the tendon injury site. Prior to injection of Arthrex ACP Tendo, the application site can be anesthetized with 1 ml lidocaine or Marcaine.



ACP/VergenixSTR



Homogenization



Ready for injection!

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# Arthrex ACP®

## Autologous Conditioned Plasma

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There is a growing interest in the use of autologous blood products, such as platelet-rich plasma (PRP), for a number of orthopedic therapies, as growth factors released by platelets contained in the blood plasma can support the healing process. The unique Arthrex ACP double-syringe system offers a time-saving solution for the sterile separation of non-homogenous liquids and, in particular, for the production of an autologous conditioned plasma enriched in platelets and growth factors. Withdrawal of blood from the human body with the Arthrex ACP double-syringe system is simple, only requiring a commercially available cannula with a Luer lock connection.

### Mechanism of ACP

The blood plasma obtained with the Arthrex ACP double-syringe system contains a platelet concentration increased by about two to three times.<sup>1</sup> Platelets are known to release various proteins, including growth factors, when activated. These growth factors are required for healing in a variety of tissue types and they appear to work synergistically.<sup>2, 3, 4</sup>

### Arthrex ACP® – Features and Benefits

- Two-in-one – unique double-syringe system for the preparation of autologous conditioned plasma
- Time-saving – ACP preparation can be performed within minutes
- Closed system – enables use in a clinic or under sterile conditions in an OR
- Safe and easy – the double-syringe design allows for easy, convenient, and safe handling of ACP

### Major Effects of Growth Factors

- Induce proliferation and differentiation of various cell types<sup>5</sup>
- Enhance production of matrix (e.g., collagen, proteoglycan production)<sup>6</sup>
- Stimulate angiogenesis and chemotaxis<sup>7</sup>

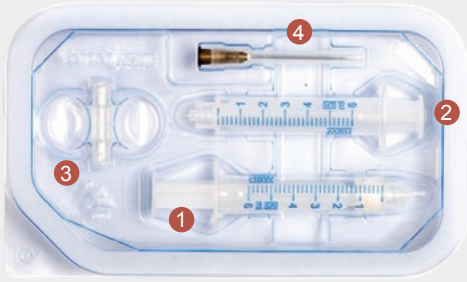
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# Vergenix™STR

## Recombinant Human Collagen Type I

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VergenixSTR, produced by a proprietary manufacturing process, is a recombinant human collagen (rhCollagen) extracted from tobacco plants engineered to produce type I human collagen identical to the native type I collagen produced by the human body. Collagen plays a crucial role in tissue repair processes and is therefore an ideal scaffold material. However, depending on the source of the collagen, structural differences exist, directly influencing the overall effectiveness of the collagen scaffold in tissue repair and healing processes. Collagen scaffolds based on VergenixSTR rhCollagen offer many advantages when compared to the bovine extracted collagen scaffolds. For example, only collagen, such as the rhCollagen, forming a perfect, undamaged triple helix can provide the optimum amount of cell-binding capacity domains. In addition, the 3D matrix and collagen fiber alignment also influence the cell-binding properties and therefore cell proliferation. Collagen scaffolds based on VergenixSTR offer superior biofunctionality and cell-binding properties leading to increased cell proliferation and faster tissue healing.<sup>8</sup>



- 1 VergenixSTR syringe
- 2 Empty syringe
- 3 Luer lock connector
- 4 19G needle

### Advantages of Vergenix™STR Recombinant Human Collagen<sup>8, 11, 12, 13</sup>

#### Bio-Functionality

- Accelerated cell proliferation
- Faster tissue healing

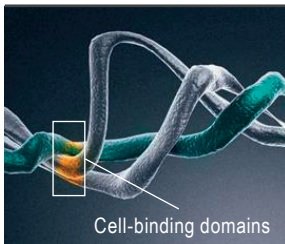
#### Superior Homogeneity

- Increased stability
- Aligned structures
- Reproducible and thermally stable

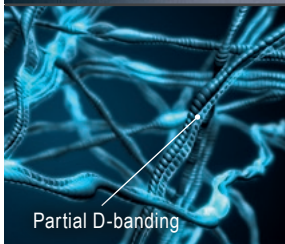
#### Safety and Purity

- Non-allergenic
- Non-immunogenic
- No pathogens

### Tissue-Extracted (Bovine/Porcine)<sup>8, 9</sup>



- Partially denatured (crosslinked)
- Low cell-binding domains

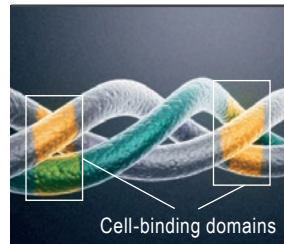


- Partially functional 3D matrix
- Thick fibers → low surface area

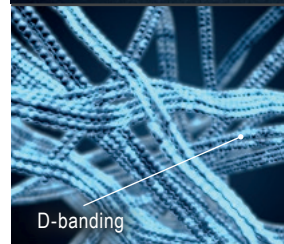


- Slow cell proliferation and slow tissue repair
  - Foreign body response
  - Edema
  - Inflammation

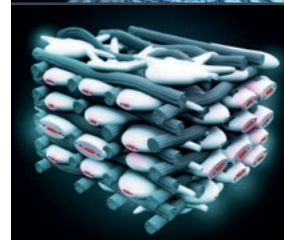
### Human Plant-Derived<sup>8, 10</sup>



- Perfect triple helix
- High cell-binding domains

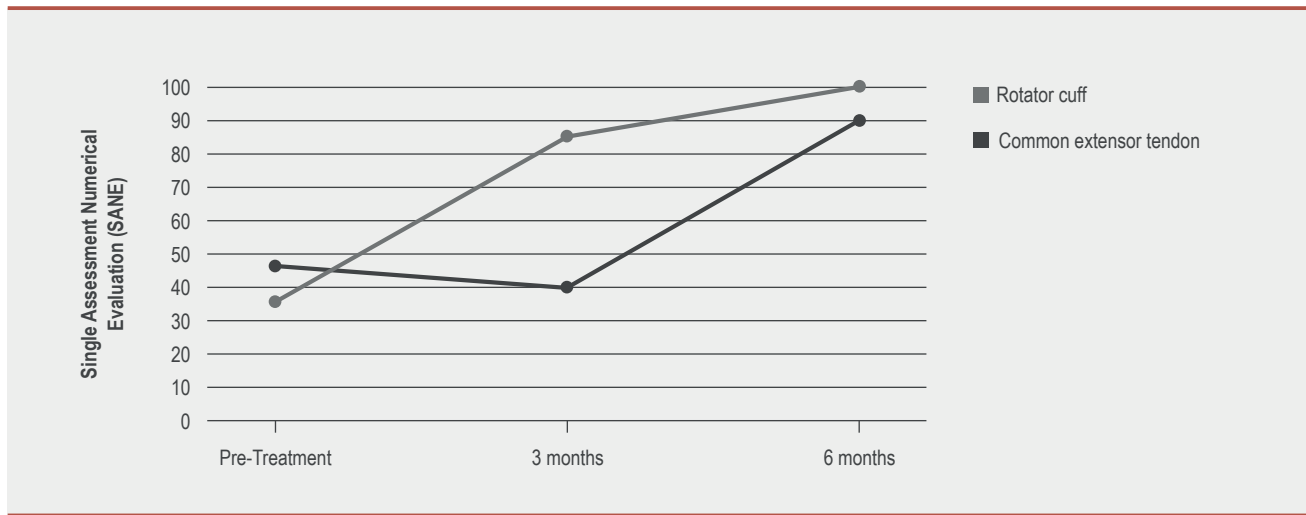
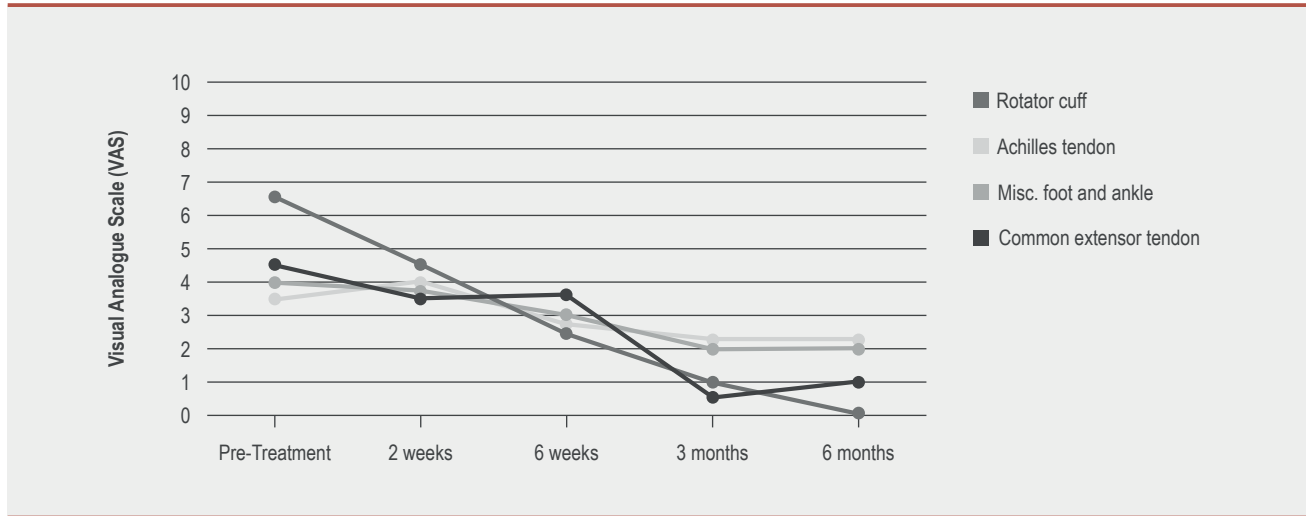


- Fully functional 3D matrix
- Thin fibers → high surface area



- Fast cell proliferation and fast tissue repair

**Arthrex ACP® Tendo European Case Series<sup>15</sup>**



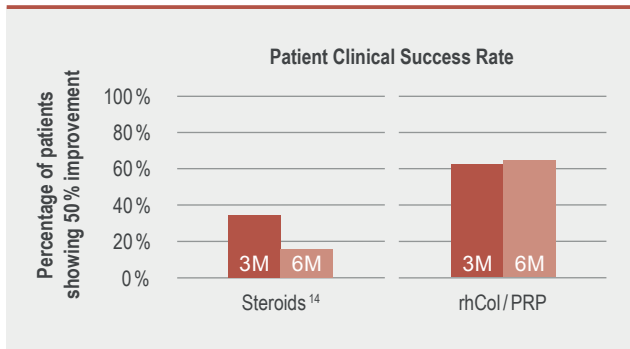
**Design**

- Case series in nine centers with 24 patients
- Indications: tendinopathy (different locations)
  - Rotator cuff
  - Achilles tendon
  - Foot and ankle (Peroneal tendon, tibialis tendon)
  - Common extensor tendon
- One-off injection with Arthrex ACP Tendo follow-up after two and six weeks, three and six months with Arthrex SOS (indication-specific pain and functionality questionnaires)

**Results**

- Considerable reduction in pain in all patient groups just two weeks after treatment
- This positive trend continued up to the last follow-up after six months
- The functionality in the patient groups with epicondylitis and partial articular supraspinatus tendon avulsion achieved almost normal values after six months

## Clinical Study – Epicondylitis \*



### Design

- Prospective, open-label, single-arm, multicenter study with 40 patients
- Each patient received a single injection of rhCollagen/PRP
- Follow-up time points: one, two, three and six months
- Endpoints include:
  - Functional recovery (PRTEE)
  - Arm strength (grip test with dynamometer)
  - Quality of life (SF-12 questionnaire)

### Results

- Functional recovery and pain improvement already at the three-month follow-up for the majority of the patients (N = 39; reduction in PRTEE score:  $\geq 25\%$  for 74% of patients;  $\geq 50\%$  reduction for 62% of patients)
- Further functional recovery and pain improvement at the six-month follow-up (N = 36; reduction in PRTEE score:  $\geq 25\%$  for 86% of patients;  $\geq 50\%$  reduction for 64% of patients)
- Significant quality of life improvement starting two months post treatment (result obtained via SF-12 questionnaire)
- Significant improvement in arm strength starting one month post treatment (result obtained via grip test)

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15. Christoph Elser et al. ACP Tendo-Plant Derived Human Collagen Scaffold Combined With ACP for the Treatment of Tendinopathy—A European Case Series. Poster No. 1216 presented at: ORS 2018 Annual Meeting; March 12, 2017; New Orleans, LA

## Ordering Information

Product Description	Item Number
Vergenix™STR soft tissue repair matrix	STR-303
<b>Arthrex ACP® Double-Syringe System</b>	
Arthrex ACP® double syringe	ABS-10014
Arthrex ACP® kit serie I	ABS-10011
<b>Drucker Centrifuge</b>	
6-tube horizontal general purpose centrifuge (human use)	HORIZON 24-AH
<b>Hettich Centrifuge</b>	
Centrifuge Hettich Rotofix 32A with swing out rotor, 220 V	1206-Art
Centrifuge Hettich Rotofix 32A with swing out rotor, 110 V	1206-01-Art
Bucket for Hettich Rotofix 32A	1491
Screw cap for Hettich bucket	1492
Counterweight for centrifugation of Arthrex ACP® double syringe, 15 ml	ABS-10027
<b>Accessories</b>	
Cart for centrifuge, 45 cm	KU.1079.800

*An anticoagulant can be ordered on request.*