Therapeutic Goods (Medical Devices—Authorised Supply) Rules 2022

I, Michael Wiseman, as delegate of the Minister for Health and Aged Care, make the following rules.

Dated 19 December 2022

Michael Wiseman
Assistant Secretary, International Regulatory Branch
Medicines Regulation Division
Health Products Regulation Group
Department of Health and Aged Care

Contents

1 Name

This instrument is the *Therapeutic Goods (Medical Devices—Authorised Supply) Rules 2022*.

2 Commencement

(1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

Commencement information		
Column 1	**Column 2**	**Column 3**
Provisions	**Commencement**	**Date/Details**
1. The whole of this instrument.	The day after this instrument is registered.	

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

(2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

This instrument is made under subsection 41HC(6) of the *Therapeutic Goods Act 1989*.

4 Definitions

Note: A number of expressions used in this instrument are defined in subsection 3(1) of the Act, including the following:

(a) health practitioner;
(b) included in the Register;
(c) medical device;
(d) Register;
(e) sponsor;
(f) supply.

In this instrument:

Act means the *Therapeutic Goods Act 1989*.

SAS Guidance means the document titled *Special Access Scheme Guidance for health practitioners and sponsors* (Version 1.1, September 2017) published by the Therapeutic Goods Administration, as in force or existing at the commencement of this instrument.

Note: The SAS Guidance is published at www.tga.gov.au.

Therapeutic Goods Administration has the same meaning as in the *Therapeutic Goods Regulations 1990*.

5 Authorisation

Supply by a specified health practitioner

(1) A health practitioner specified in column 4 of an item in the table in Schedule 1 is authorised to supply a kind of medical device to a patient of that practitioner where:
  (a) the kind of medical device is specified in column 2 of that item; and
  (b) the supply is for the purpose specified in column 3 of that item; and
  (c) the conditions specified in subsection (2) are satisfied.

(2) The health practitioner must:
  (a) inform the patient, or a parent or guardian of the patient, that the kind of medical device is not included in the Register; and
  (b) obtain informed consent from the patient, or a parent or guardian of the patient, in relation to, and before, the supply of the kind of medical device; and
  (c) supply the kind of medical device in accordance with good medical practice; and
  (d) if the health practitioner becomes aware that the patient has suffered an adverse event in relation to the kind of medical device—notify the Therapeutic Goods Administration and the sponsor of the kind of medical device about the adverse event in accordance with the reporting guidelines set out in the SAS Guidance; and
  (e) if the health practitioner becomes aware of a defect in the kind of medical device—notify the Therapeutic Goods Administration and the sponsor of the kind of medical device in accordance with the reporting guidelines set out in the SAS Guidance.

Supply to a patient of a specified health practitioner

(3) A health practitioner is authorised to supply a kind of medical device to a patient of a health practitioner specified in column 4 of an item in the table in Schedule 1 (the ***treating practitioner***) where:
  (a) the kind of medical device is specified in column 2 of that item; and
  (b) the supply is requested by the treating practitioner; and
  (c) the supply is for the purpose specified in column 3 of that item; and
  (d) the conditions specified in subsection (4) are satisfied.

(4) The health practitioner supplying the medical device must:
  (a) if the health practitioner becomes aware that the patient has suffered an adverse event in relation to the kind of medical device—notify the Therapeutic Goods Administration and the sponsor of the kind of medical device about the adverse event in accordance with the reporting guidelines set out in the SAS Guidance; and

(b) if the health practitioner becomes aware of a defect in the kind of medical device—notify the Therapeutic Goods Administration and the sponsor of the medical device in accordance with the reporting guidelines set out in the SAS Guidance.

6 Repeals

Each instrument that is specified in Schedule 2 is repealed as set out in the applicable items in that Schedule.

Schedule 1—Medical devices authorised for supply

Note: See section 5.

Specified therapeutic goods			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Kind of medical device**	**Purpose**	**Health practitioner**
1	14/16 Taper Femoral Heads – Oxinium – Smith & Nephew (71342280 – 71342368)	revision hip arthroplasty	orthopaedic surgeon
2	Aequalis PerForm Plus Reversed Glenoid – Wright Medical	for arthroplasty of the shoulder	orthopaedic surgeon
3	Aequalis PerForm Reversed Glenoid – Wright Medical	for arthroplasty of the shoulder	orthopaedic surgeon
4	AltiVate Reverse Shoulder system – DJO Global	for arthroplasty of the shoulder	orthopaedic surgeon
5	Biodesign Enterocutaneous Fistula Plug	for repair of enterocutaneous fistulae	general surgeon
6	BlastGen (Product No. 1205)	culture of embryos from the 4-8 cell stage through to the blastocyst stage; or embryo transfer	obstetrics and gynaecology specialist
7	CelGro Type I/III collagen scaffold – Orthocell	articular cartilage repair: collagen scaffold for use with autologous chondrocyte implantation (ACI) to knee (including patellofemoral) and ankle joint; or augmentation of rotator cuff tendon repair	orthopaedic surgeon
8	CollaCote Dressing	for haemostasis or to protect the wound surface during dental procedures	dental practitioner
9	CollaPlug Absorbable Collagen Wound Dressing	for haemostasis or to protect the wound surface during dental procedures	dental practitioner
10	CollaTape Absorbable Collagen	for haemostasis or to protect the wound surface during dental procedures	dental practitioner
11	Duraloc Acetabular Cup System – Hip Insert/Liner – Johnson & Johnson t/a DePuy Synthes	revision hip arthroplasty	orthopaedic surgeon
12	EmbryoGen (Product No. 1203)	fertilisation and culture until the 2-8 cell stage; or embryo transfer at day 2 or 3	obstetrics and gynaecology specialist

Specified therapeutic goods			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Kind of medical device**	**Purpose**	**Health practitioner**
13	EmbryoGen & BlastGen (Product No. 1206)	culture of embryos until the 2-8 cell stage (Embryogen) and culture of embryos from the 4-8 cell stage through to the blastocyst stage (Blastgen); or embryo transfer	obstetrics and gynaecology specialist
14	EmbryoGen V2 (Product No. 1204)	culture of human embryos until the 2-8 cell stage; or embryo transfer at day 2 or 3	obstetrics and gynaecology specialist
15	Endotine Forehead	for use in subperiosteal browplasty surgery	plastic surgeon
16	Endotine Midface	for use in subperiosteal midface suspension surgery	plastic surgeon
17	GM508 CultActive	for investigation of fertilization failure after previous ICSI-cycles	obstetrics and gynaecology specialist
18	Ilex Skin Protectant	for use on a variety of dermal wounds and stomal irritations as a topical skin barrier	medical practitioner; nurse practitioner
19	Insall/Burstein II Modular Knee System - Posterior Stabilised Tibial Articular Surface – Zimmer Biomet (00522003101 – 00522003506)	revision knee arthroplasty	orthopaedic surgeon
20	Jupiter Sternal Protection Device	for use following median sternotomy incisions to add a protective layer over the entire cut surfaces of the sternal bone	cardiothoracic surgeon
21	MG II Total Knee System - Tibial Articular Surface – Zimmer Biomet (00511002309 – 00511005323)	revision knee arthroplasty	orthopaedic surgeon
22	M/G Unicompartmental Knee System - Tibial Articulating Surface – Zimmer Biomet (00578804008 – 00578808014)	revision knee arthroplasty	orthopaedic surgeon
23	Natural Knee II System – Durasul PE Congruent Tibial Insert – Zimmer Biomet (620108809 – 620110916)	revision knee arthroplasty	orthopaedic surgeon

Specified therapeutic goods			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Kind of medical device**	**Purpose**	**Health practitioner**
24	NexGen Complete Knee Solution – Cruciate Retaining (CR) Articular Surface – Zimmer Biomet (00597002009 – 00597005020)	revision knee arthroplasty	orthopaedic surgeon
25	NexGen Complete Knee Solution Legacy PS - Articular Surface – Zimmer Biomet (5996-020-09 to 00-5996-022-23 AND 00-5996-030-09 to 00-5996-051-20)	revision knee arthroplasty	orthopaedic surgeon
26	NexGen Complete Knee Solution Mobile Bearing Knee System - Articular Surface – Zimmer Biomet (00594203109 – 00594207217)	revision knee arthroplasty	orthopaedic surgeon
27	NexGen Complete Knee Solution – Posterior Stabilized (PS) Articular Surface – Zimmer Biomet (00598202010 – 00598205123)	revision knee arthroplasty	orthopaedic surgeon
28	Omnifit Crossfire Series II Cup Insert – Stryker Orthopaedics (2041C2240 - 2041C3274)	revision hip arthroplasty	orthopaedic surgeon
29	Primetech Piezo Micro Manipulator and microinjection pipettes	in vitro fertilisation	obstetrics and gynaecology specialist
30	Pro Osteon® Bone Graft Substitute 200R	for use as a bone graft substitute only for bony voids or gaps that are not intrinsic to the stability of the bony structure	medical practitioner; dental practitioner
31	Pro Osteon® Bone Graft Substitute 500R	for use as a bone graft substitute only for voids or gaps that are not intrinsic to the stability of the bony structure	medical practitioner
32	Quintip Individual Skin Test System	for allergy skin testing using puncture to apply the test extract	medical practitioner
33	Reflection Ceramic Acetabular System - Reflection Biolox Forte Ceramic Acetabular Liner	revision hip arthroplasty	orthopaedic surgeon

Specified therapeutic goods			
Column 1	**Column 2**	**Column 3**	**Column 4**
Item	**Kind of medical device**	**Purpose**	**Health practitioner**
	– Smith & Nephew (71338146 – 71338456)		
34	Regeneten Bioinductive Implant – Bone Anchors with Arthroscopic Delivery System	rotator cuff surgery	orthopaedic surgeon
35	SeleXys Hip System – Inlay Bionit2 – Mathys Orthopaedics (55462803 – 55463612)	revision hip arthroplasty	orthopaedic surgeon
36	Trilogy AB Alternate Bearing Shell Insert – Zimmer Biomet (00640502601 – 00640503206 AND 00641502802 – 00641503206)	revision hip arthroplasty	orthopaedic surgeon

Schedule 2—Repeals

Note: See section 6.

Therapeutic Goods (Medical Devices—Authorised Supply) Rules 2020

1 The whole of the instrument

Repeal the instrument