

FLIP-OFF[®] CCS SEAL

Clean • Certified • Sterilised



WEST Pharmaceutical
SERVICES 

West's Flip-Off® CCS Seals – The Solution for Aseptic Processing

Pharmaceutical manufacturers can't afford to expose their drug products to risks associated with unsuitable packaging components. This is especially true in today's manufacturing environment where emerging regulatory guidelines require filling operations to use clean components in a sterile working area.

To help comply with regulatory guidances, pharmaceutical manufacturers the world over have relied on packaging components designed and manufactured by West Pharmaceutical Services. West's products have set standards for pharmaceutical closures.

Now, West is expanding its leadership position with the introduction of *Flip-Off CCS* seals; clean, certified, sterilised.

Flip-Off CCS seals address pharmaceutical manufacturers' needs for secondary closures in aseptic filling operations. CCS seals are certified with regard to bioburden and cleanliness and are designed to be used in a sterile manufacturing environment. *Flip-Off CCS* seals are available in 13mm and 20mm sizes.

Why Flip-Off CCS?

In September 2004, the United States Food and Drug Administration (FDA) published a new guidance for aseptic processing. Consequently, there is clearer guidance and direction with regard to containers and closures. The use of CCS provides a higher assurance of not contaminating the final drug product during the crimping and sealing process. A stringent clean manufacturing practice should include pharmaceutical seals that are cleaned and sterilised prior to use.

Further, the EC Guide of GMP, Annex 1, addresses appropriate measures to minimise the particulate contamination of the end product. Specific reference is made to the sterilisation and handling of components, containers, equipment and any other articles required in an aseptic work environment so contamination is not introduced into the clean area.



The CCS Advantage

Flip-Off CCS seals are manufactured to the same exacting standards used for West's *Flip-Off* seals. But the validated *Flip-Off CCS* manufacturing process offers pharmaceutical companies much more: CCS seals are able to meet emerging requirements for capping vials in a clean room.

The West production process controls bioburden and particles by not exceeding the following limits:

Particle burden	≤ 10 Proved Clean Index
Bioburden	≤ 5 Colony Forming Units per 100 cm ²

This guarantees that the subsequent validated sterilisation process reliably results in a sterile product.



The Flip-Off CCS Seal Production Process Assures a Clean, Certified, Sterilised Product

- The *Flip-Off* buttons are manufactured from a gamma-stable polypropylene resin.
- The buttons are washed in a pharmaceutical washer before they are assembled to the aluminum shell.
- The aluminum shells are treated with a specially developed coating in order to avoid abrasion particles.
- The buttons are assembled to the shells by machines designed for clean applications in a controlled environment.
- Samples are taken to measure particles and bioburden.
- *Flip-Off CCS* seals are double-packed in certified heat-sealed polyethylene bags.
- The bags are protected by an additional polyethylene bag to reduce particulate at the customer's site.
- *Flip-Off CCS* seals are gamma irradiated.



The Standard in Pharmaceutical Seals

West's *Flip-Off CCS* seals provide manufacturers with the same benefits they have enjoyed with standard *Flip-Off* seals.



- Excellent performance on high-speed filling lines
- A range of colours for lacquered aluminum shells and plastic buttons for product differentiation
- An enhanced button surface for decoration and lot and date coding
- Tamper-evident properties
- Easy, one-hand removal

Choose Flip-Off CCS Seals for Your Aseptic Processing

To find out how to incorporate *Flip-Off CCS* seals into your manufacturing process, contact your West Pharmaceutical Services account manager. You may also send an email to TCS.Europe-AsiaPacific@westpharma.com.



Global Sales Offices

Argentina

Calle 35 N 5800
Villa Ballester - C.P. 1653
Buenos Aires
Tel: +54 11-4849-0600
Fax: +54 11-4738-0600

Australia

1/20 Narabang Way
Belrose
NSW 2085
Tel: +61 2 9986 1410
Fax: +61 2 9986 1460

Brazil

Rio de Janeiro Office
Rua Alberto de Campos
40 - apto. 1508
Ipanema - Rio de Janeiro - RJ - Brazil
CEP 22411-0
Phone/fax: 55 21 2513-5500

São Paulo Office
Av. Nossa. Sra. das Graças, 115
Serraria - Diadema - São Paulo
CEP 09980-000
Tel: +55 11 4055 6060
Fax: +55 11 4055 6040

China

Beijing Office
4-1-407, No. 3 Wang Jing Zhong
Huan Nan Lu, Chao Yang District
Beijing, 100102
Tel: +86 10 84711541
Fax: +86 10 64733429

Shanghai Office
RM 201 Shanghai
TAIPAN Business Centre
No. 20 Dong Hu Road
Shanghai, 200031
Tel: +86 21-54030627
Fax: +86 21-54044107

Shenzhen Office
#7, Great Wall Mension
Room 1502, Suite B
Shenzhen 518028
Tel: +86 755-3361231
Fax: +86 755-3328476

Colombia

World Trade Center Bogotá
Calle 100 No. 8A-49
Torre B Oficina 609
Santafé de Bogotá, D.C.
Tel: +57 1 655 9990
Fax: +57 1 655 9985

Denmark

51, Fuglevangsvej
8700 Horsens
Tel: +45 (7561) 6000
Fax: +45 (7562) 7028

England

Bucklers Lane
St. Austell
Cornwall, PL25 3JU
Tel: +44 (1726) 6 35 63
Fax: +44 (1726) 22 32 19

France

ZA des Côteaux du Bel-Air
29-31 Boulevard de la Paix
78100 Saint Germain en Laye
Tel: +33 (1) 39 21 54 00
Fax: +33 (1) 34 51 36 52

Germany

Stolberger Strasse 21 - 41
52249 Eschweiler
Tel: +49 (24 03) 7960
Fax: +49 (24 03) 796 250

India

Hyderabad Office
#204, Ramashree Enclave
12-8-254/7, Mettuguda
Hyderabad - 500017
Tel/Fax: +91 40-27820272

Mumbai Office
Vakharia Bhuvan, Joshi Lane
Ghatkopar (East)
Mumbai 400077
Tel/Fax: +91 22-25124234

Italy

Piazza Duca D'Aosta 8
I-20124 Milano
Tel: +39 02-6703079
Fax: +39 02-6691536

Japan

Daikyo Seiko, Ltd.
38-2, Sumida 3-Chome,
Sumida-Ku
Tokyo 131-0031
Tel: +81 3-3614-5461
Fax: +81 3-3610-1241

Mexico

Boulevard Manuel Ávila
Camacho No. 6
A. Despacho 708
Col. El Parque Naucalpan
Estado de México
México City C.P. 53390
Tel: +(5255) 5580-2006
Fax: +(5255) 5557-2235

Serbia

Cara Urosa 541
Rimski Jarak bb
Beograd
Kovin 11000/26200
Tel: +381 113285 430

Singapore

15 Joo Koon Circle
Jurong 629046
Tel: +65 6 862-3400
Tel: +65 6 862-3401
Fax: +65 6 861-0316

Spain

Sierra de Albarracín, 1 - Local 3
28831 San Fernando de Henares
Madrid
Tel: +34 (91) 656-1415
Fax: +34 (91) 656-1763

Thailand

134/28 Moo 9
Bangkrui Nonthaburi 11130
Tel: +66 2-976 1468
Fax: +66 2-976 1478

United States

Global Headquarters
101 Gordon Drive
Lionville, PA 19341
Tel: +1 (610) 594-2900
Fax: +1 (610) 594-3000

Venezuela

Av. Pascuale Giorgio
(antes 3ra transversal)
edificio Centro Industrial Giorgio
piso 4, oficina 4-A
Los Ruices, Caracas
Tel: +58 212 237 7385
+58 212 237 8203
+58 212 232 8745
Fax: +58 212 237 7959



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